UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA, et al., *ex rel.* MATTHEW A. FITZER, M.D.,	*	
Plaintiff-Relator,	*	Civil Action No.: 1:17-cv-00668-SAG
v.	*	Fourth Amended Complaint Jury Trial Demanded
ALLERGAN, INC., et al.,	*	
Defendants.	*	

* * * * * * * * * * *

FOURTH AMENDED COMPLAINT

1. COMES NOW Plaintiff-Relator Matthew A. Fitzer, MD ("Plaintiff-Relator" or "Dr. Fitzer"), on behalf of the United States of America, pursuant to the *qui tam* provisions of the False Claims Act (FCA), 31 U.S.C. § 3729, et seq. as amended, and the state governments of California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and Wisconsin pursuant to the *qui tam* statutes of their respective states against Defendants Allergan, Inc. ("Allergan") and Apollo Endosurgery, Inc. ("Apollo") (collectively, "Defendants"), by and through his undersigned attorneys, Nichols Kaster, PLLP and Price Benowitz, LLP, alleging as follows:

PRELIMINARY STATEMENT

2. This case is about an illegal kickback scheme employed by Defendants in marketing the LAP-BAND® medical device. Defendants provided bariatric surgeons with valuable advertising services at no cost and used a volume-based quota to induce referrals of its

product. Indeed, for years Defendants illegally incentivized surgeons to recommend and order procedures for the LAP-BAND® device by either providing or withholding valuable marketing services through their www.lapband.com website based on a usage quota of their device. Surgeons then filed claims for reimbursement of LAP-BAND® procedures with government programs such as Medicare and Medicaid. Defendants' scheme corrupted surgeon's medical judgment, breaching the promise providers make to state and federal governments in their submissions of claims in violation of the False Claims Act.

3. The LAP-BAND® is a gastric-band medical device owned by Allergan, and later, Apollo, that enjoyed brief popularity as a treatment for morbid obesity.

4. Aggressive marketing propelled the success of the LAP-BAND®, making it the most performed weight-loss operation in the United States by 2008.

5. The LAP-BAND® monopolized the gastric-band market, competing with only one other gastric-band device starting in 2007, the Realize® band, manufactured and sold by Ethicon Endo-Surgery. The two different bands each had their own separate training and certification programs that the FDA required to be completed before surgeons could perform procedures using the specific band.

6. Allergan's advertising program was well-funded, nationwide, and included television, billboards, print, and online search. Most of their ads had the visible objective of funneling traffic to its renowned www.lapband.com website and directly to a popup physician locator, which drove potential patients to surgeons in their area willing to implement the device.

7. Defendants invested heavily in optimizing this website and promoted it in its commercials and other marketing materials for the purpose of driving traffic to the site, and

ultimately to a surgeon, with much success. But despite these investments, Defendants did not charge surgeons for inclusion on www.lapband.com and related benefits.

8. Surgeons simply requested to be included, provided their profile information and then watched the business roll in.

9. In Dr. Fitzer's experience during the relevant time period, it was common knowledge among bariatric surgeons that the www.lapband.com locator was a valuable practice-building resource. And Allergan made sure that surgeons on the locator were aware of the value of their free marketing by sending them email alerts showing leads generated from the locator through seminar sign-ups and providing a lead tracker spreadsheet for surgeons to use on their own.

10. This website helped the LAP-BAND® become a household name and, briefly, the most-often performed weight-loss procedure in the United States.

11. The distinction was short-lived, however, because a deluge of adverse long-term outcomes reports became public. Long-term outcomes, it turned out, were the critical flaw of gastric bands, and mounting clinical evidence demonstrated that fact ever more vividly. Surgeons and patients began to complain about leaks and defects, which required re-operation and even explantation (removal). By 2012, a clear consensus had solidified within the professional community that the LAP-BAND® was, if not obsolete, an inferior option compared to other weight-loss procedures.

12. Unsurprisingly, the business outlook for the product turned grim. By 2012, LAP-BAND® sales revenue was in its fourth year of decline, down an astonishing 50% from the 2008 high-water mark, and it showed no sign of bottoming.

13. Allergan responded by announcing it intended to sell the LAP-BAND® product line. The first quarter of 2013 came and went without a sale, and LAP-BAND® market share continued its precipitous drop.

14. It was at this extraordinary moment—by all appearances the darkest hour for the LAP-BAND®—that Allergan looked desperately for revenue opportunities to shore up the failing LAP-BAND® business.

15. Allergan would henceforth demand a specific level of product loyalty from physicians in exchange for giving them free advertising services through the www.lapband.com surgeon locator. The rent, it seemed, was due.

16. Allergan enacted a policy of restricting participation in their marketing service, to only those providers who completed at least 40 LAP-BAND® specific procedures per year. This was, and remained for years, a quota-based illegal inducement.

17. Allergan purged the physician locator of surgeons with low LAP-BAND® usage, which by 2013 was most of America's weight loss surgeons. The website did not include Dr. Fitzer, as well as the entire surgical staffs of some of the country's preeminent bariatric surgery programs. Altogether, Allergan quietly purged more than 1,000 surgeons—which represented a substantial percentage of the overall locator. Publicly, Allergan acted as though nothing had happened, never posting reasons for inclusion on or exclusion from the website physician locator.

18. The surgeons that remained were those with the highest LAP-BAND® usage.

19. In enacting a quota, Allergan sought to increase sales in two ways: (1) by further incentivizing surgeons to perform more LAP-BAND® procedures and so to preserve or restore their position on the locator--even if doing so required overriding what was in the best interest of the patient, and (2) by ensuring that the surgeons getting referrals were the ones loyal to the LAP-

BAND®. This way, the potential patients Allergan sought to funnel to www.lapband.com would be connected to surgeons who were all but certain to perform a procedure using a LAP-BAND®.

20. Dr. Fitzer learned of the secret quota system that was withheld from potential patients from his Allergan account manager, and its existence was confirmed to him by an Allergan Vice President of Sales. If forty of his patients accepted a tainted recommendation to undergo LAP-BAND® surgery, he was in. Less, and he was out.

21. Surgeons were faced with a choice. They either had to give up a valuable business resource or allow a medical device company to taint their independent judgment in circumstances where the LAP-BAND® may not be the most medically appropriate choice all to satisfy the quota.

22. This pressure is not only problematic for the doctor-patient relationship; it is also problematic for the federal and state governments. Most bariatric surgeons (like Dr. Fitzer) have some percentage of patients on federal healthcare programs such as Medicare or Medicaid. When the government agrees to reimburse medical claims through these programs, it bargains for more than just a particular product or medical service. These claims must also be medically necessary, and the government relies on providers' professional judgment to inform this analysis. When that judgment is tainted, the government does not get the benefit of its bargain.

23. The inducement offered here was substantial. Allergan's marketing savvy generated enormous patient interest for their chosen doctors, some of whom saw their *Medicare* billings for LAP-BAND® surgery more than double under the quota system. Dr. Fitzer knew a LAP-BAND® surgeon, Dr. Robert Pinnar, who attributed his entire bariatric practice to www.lapband.com referrals. Defendants' policy strongly incentivized surgeons to generate more LAP-BAND® sales. There was no other way to get so much free marketing support.

24. Dr. Fitzer was outraged when he learned of Allergan's scheme, and he protested.

25. He debated the legality of the quota with an Allergan Vice President. Dr. Fitzer attempted to explain to Allergan officials every way he could—verbally and in writing—how the scheme was a naked violation of the Anti-Kickback Statute. Allergan rebuffed several requests to acknowledge their conduct in writing, and they proceeded with the scheme—full steam ahead. Dr. Fitzer was left behind.

26. Allergan did finally manage to sell the LAP-BAND® product line.

27. In December 2013, some 100 Allergan sales personnel, including the aforementioned Vice President, transferred, or were loaned, to Apollo with its purchase of the LAP-BAND® product line.

28. Apollo maintained Allergan's scheme, providing valuable internet advertising through the physician locator at no cost to surgeons and managed the scheme with a quota based on usage.

29. After years of implementing the quota without public acknowledgment, Apollo began disclosing its terms on the website in a half-hearted attempt to feign compliance with Safe Harbor standards.

30. When it suited Apollo's bottom line, it ignored its own terms.

31. Neither Defendant ever reinstated Dr. Fitzer on the LAP-BAND® physician locator.

32. The valuable marketing services the Defendants provided certain surgeons for free in exchange for their high-level usage of the LAP-BAND® amounted to a rewards program. It qualifies as an unlawful kickback.

33. In running their scheme, Defendants caused federal and state health insurance programs, including but not limited to, Medicare and Medicaid, to pay false or fraudulent claims for reimbursement associated with Defendants' LAP-BAND® product.

34. Defendants in essence purchased surgeons' medical judgment.

35. A violation of the federal Anti-Kickback Statute creates direct liability under the federal False Claims Act.

36. Defendants knew and/or reasonably foresaw, that their illegal financial inducements would cause the submission of thousands of claims to government healthcare programs associated with the LAP-BAND® medical device that were not eligible for reimbursement.

37. Accordingly, Plaintiff-Relator files this action to recover penalties and damages on behalf of himself and the above-listed governments.

JURISDICTION AND VENUE

38. This action arises under the Federal False Claims Act, 31 U.S.C. § 3729, et seq.

39. This Court maintains subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331, and supplemental and pendant jurisdiction.

40. Dr. Fitzer also brings this action on behalf of the governments of California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and Wisconsin, hereinafter referred to collectively as "the States."

41. Dr. Fitzer brings this action on behalf of the States for the Defendant's violations of Cal. Gov't Code § 12650, et seq.; Colo. Rev. Stat. § 25.5-4-303.5, et seq.; Conn. Gen. Stat. § 4-

274, et seq.; Del. Code Ann. Tit.6. § 1201, et seq.; D.C. Code § 2-381.01, et seq.; Fla. Stat. Ann. § 68.081, et seq.; Ga. Code. Ann. § 49-4-168, et seq.; Haw. Rev. Stat. Ann. § 661-21, et seq.; 740 Ill. Comp. Stat. Ann. 175/1, et seq.; Ind. Code § 5-11-5.5, et seq.; Iowa Code §685.1, et seq.; La. Rev. Stat. Ann. § 46.437.1, et seq.; Mass. Ann. Laws ch.12, § 5, et seq.; Mich. Comp. Laws. Serv. § 400.601, et seq.; Minn. Stat. § 15C.01, et seq.; Mont. Code Ann. § 17-8-401, et seq.; Nev. Rev. Stat. Ann. § 357.010, et seq.; N.J. Stat. Ann. § 2A: 32C-1, et seq.; N.M. Stat. Ann. § 27-14-1, et seq.; N.M. Stat. Ann. § 44-9-1, et seq.; N.Y. State Fin. Law § 187, et seq.; N.C. Gen. Stat. § 1-605, et seq.; Okla. Stat. tit. 63, § 5053, et seq.; R.I. Gen. Laws § 9-1.1-1, et seq.; Tenn. Code Ann. § 4-18-101, et seq.; Tenn. Code Ann. § 71-5-181, et seq.; Tex. Hum. Res. Code Ann. § 36.001, et seq.; Va. Code Ann. § 8.01-216.1, et seq.; Wash. Rev. Code § 74.66.005, et seq.; Wis. Stat. § 20.931. These laws hereinafter collectively referred to as the "False Claims Acts of the States" or "State False Claims Acts".

42. Jurisdiction over State False Claims Acts claims is also conferred by 31 U.S.C. § 3732(b) in that the transactions and or occurrences described which violate the State False Claims Acts involve a common nucleus of facts as, and are related to, those that violate the Federal False Claims Act.

43. Venue is proper in this Court pursuant to 31 U.S.C. § 3732(a) because the Defendants regularly transact business in this district and did so at all times relevant to this Complaint; the False Claims Act confers national jurisdiction.

44. Plaintiff-Relator initially filed this action under seal on November 26, 2013 in the United States District Court for the District of Columbia.

45. On or about February 22, 2017, this matter was transferred to the District of Maryland on a motion by the United States.

PARTIES

I) PLAINTIFF-RELATOR MATTHEW A. FITZER, M.D

46. Plaintiff-Relator Matthew A. Fitzer, M.D. is a citizen of the United States and resides in Ashburn, Virginia.

47. Dr. Fitzer is the Director of the Virginia Bariatric Surgery Center of Herndon, Virginia, and he is a full-time bariatric (weight-loss) surgeon.

48. Dr. Fitzer was an American Society for Metabolic and Bariatric Surgery ("ASMBS") Center of Excellence Surgeon.

49. Dr. Fitzer is the metabolic and bariatric surgery director of Reston Hospital Center's MBSAQIP-accredited bariatric surgery quality improvement program.

50. Dr. Fitzer is qualified to perform bariatric surgery, specifically including the three operations that were considered the mainstream options: the Gastric Bypass, the Sleeve Gastrectomy, and the implantation of the adjustable gastric band ("AGB") more popularly known and promoted by the Defendants by its brand name, the LAP-BAND®. He also obtained a separate certification to implant the Ethicon Realize® band.

51. Dr. Fitzer obtained a B.S. in physics from Christopher Newport University, and an M.D. from Eastern Virginia Medical School.

52. Dr. Fitzer completed his general surgery residency at Memorial Health University Medical Center in Savannah, Georgia, where he developed his interest in the treatment of obesity.

53. Dr. Fitzer also underwent a year of formalized training in bariatric surgery after residency—a bariatric surgery fellowship—at the University of Missouri.

54. During this fellowship, he received intensive training by experts in how to implant the LAP-BAND® and manage LAP-BAND® patients pre- and post-operatively.

55. Dr. Fitzer entered private practice in Utica, New York and operated at St. Luke's Hospital, a Bariatric Center of Excellence.

56. With Dr. Fitzer's help, St. Luke's gained recognition from Healthgrades for the best bariatric surgery outcomes in New York State. He practiced there for five years and performed approximately 1,700 bariatric operations before returning to Virginia.

57. Dr. Fitzer moved his practice from New York to Virginia in 2012.

58. Dr. Fitzer is licensed by the Virginia Board of Medicine.

59. At the time his membership from the website was revoked by Defendant Allergan, Dr. Fitzer was the only local surgeon in their referral base who had formal Bariatric Surgery Fellowship training, to his knowledge.

60. At the time the original complaint was filed in this matter, Dr. Fitzer had performed more than 2,000 successful bariatric procedures including approximately 100 surgeries to implant the LAP-BAND®.

61. Prior to the seal being lifted, there had been no public disclosure of the allegations contained in this Complaint.

62. Dr. Fitzer is the original source of all the information contained in this Complaint within the meaning of 31 U.S.C. § 3730(e)(4)(B).

63. Dr. Fitzer has independent knowledge of all the information contained herein, and Dr. Fitzer has voluntarily provided such information to the United States as well as the above listed States prior to filing this action.

II) DEFENDANTS

64. Defendant, Allergan, Inc., hereafter "Allergan," at relevant times had a principal place of business at 2525 Dupont Drive, Irvine, CA 92612.

65. Allergan is a publicly company traded on the New York Stock Exchange under the symbol "AGN."

66. Allergan manufactured and sold the adjustable gastric band, registered under the trademark "LAP-BAND®" in the United States beginning in approximately 2005.

67. As part of promoting the LAP-BAND® service line, Allergan created, maintained, and promoted www.lapband.com, which included the web-based physician locator that allows the public to find bariatric surgeons in their area.

68. Dr. Fitzer filed his *qui tam* complaint under seal against Defendant Allergan on November 26, 2013 while it still owned the LAP-BAND® brand.

69. Defendant Apollo Endosurgery, Inc., hereinafter "Apollo", has a principal place of business at 1120 S. Capital of Texas Highway, Building 1, Suite 300 Austin, TX 78746.

70. Apollo acquired the obesity intervention division of Allergan, including the LAP-BAND® brand in or about December 2013 for $110 million.

71. According to Apollo's Form 10-K filed on March 24, 2017, the transfer of responsibility for activities related to the acquired Allergan business at issue were as follows:

- transfer of United States sales force in December 2013;
- transfer of United States distribution in September 2014;
- transfer of Europe, Canada and Australia sales force and distribution in November 2014;
- transfer of most worldwide regulatory activities in December 2014;
- transfer of product surveillance activities in October 2015;
- transfer of Brazilian sales and distribution activities in November 2015; and
- start of Costa Rica manufacturing operations in June 2016.

72. Additionally, as described below, many of Allergan's employees and executives transferred to Apollo in connection with the sale of the LAP-BAND®.

73. About 100 of Allergan's sales representatives transferred to Apollo. In January 2014, Ted Stephens, then V.P. of Global Marketing for Apollo noted, "It was a very valuable sales channel for us to have acquired, and we're now the only company of our size with a meaningful sales channel with this kind of reach."[1]

74. Among individuals known by Dr. Fitzer to have transferred to Apollo were Mark Didio, Jeff Stitely, and Paul Hickey. These three individuals were aware that Dr. Fitzer believed the quota system amounted to an illegal kickback scheme, and therefore healthcare fraud.

75. Dr. Fitzer filed an amended complaint under seal to include Defendant Apollo on August 1, 2014.

76. Apollo continued to operate the relevant website with the same or similar marketing, policies, and practices in place at least until Apollo's sale of the LAP-BAND® in December 2018, to the best of the Plaintiff-Relator's knowledge.

77. On December 17, 2018, Reshape Lifesciences, Inc. acquired the LAP-BAND® brand from Apollo. According to the acquisition annual report, Apollo retained liabilities from the time prior to the acquisition.

78. Reshape Lifesciences abandoned Defendants' quota-based inclusion criteria.

[1] Chad Swiatecki, *When thinking big pays off*, The Austin Business Journal (Jan. 31, 2014).

RELEVANT LEGAL BACKGROUND

I) THE ANTI-KICKBACK STATUTE

79. Under the Anti-Kickback Statute, it is a crime to "knowingly and willfully solicit[] or receive[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—"

> **(A)** in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> **(B)** in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program[.]

42 U.S.C. § 1320a-7b(b)(1).

80. The Anti-Kickback Statute also imposes criminal liability on persons who "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" to induce a person

> **(A)** to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> **(B)** to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program[.]

42 U.S.C. § 1320a-7b(b)(2).

81. Additionally, the Anti-Kickback Statute imposes criminal liability on any person who "knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program[.]" 42 U.S.C. § 1320a-7b(a).

82. Medicare and Medicaid each qualify as a "Federal health care program" as defined in the Anti-Kickback Statute. 42 U.S.C. § 1320a-7b(f).

83. The Anti-Kickback statute defines "remuneration" to include in part "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6).

84. "Remuneration" includes anything of value. See, e.g., Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952-01 (Jul. 29, 1991) ("Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever."); see also United States ex rel. Gohil v. Sanofi U.S. Servs. Inc., No. CV 02-2964, 2020 WL 6682483, at *10 (E.D. Pa. Nov. 12, 2020) ("Courts generally interpret the term 'remuneration' 'expansively to include anything of value in any form whatsoever.'" (internal citation omitted)).

85. For example, the Office of the Inspector General of the Department of Health and Human Services ("HHS-OIG"), in 1994, issued a special fraud alert, stating the Anti-Kickback Statute could be implicated by

> [a]ny prize, gift or cash payment, coupon or bonus (e.g., airline discounts and related travel premiums), offered to physicians and/or suppliers ... in exchange for, or based on, prescribing or providing specific prescription products. These items are particularly suspect if based on value or volume of business generated for the drug company.

OIG Special Fraud Alerts (Dec. 19, 1994).[2]

86. In 2003, HHS-OIG stated that "[a]ny time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent

[2] https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html (last visited May 10, 2021).

to induce or reward referrals." HHS-OIG, Guidance to Pharmaceutical Manufacturers 28 (April 2003).[3]

87. One of the purposes of the Anti-Kickback Statute is to help "protect patients from inappropriate medical referrals by providers who may be unduly influenced by financial incentives." OIG Advisory Opinion No. 98-16.[4]

88. The integrity of the patient-physician relationship is comprised when anyone including companies such as these Defendants, provide illegal remuneration to physicians in order to induce them to use the company's products.

89. A person "need not have actual knowledge of [the Anti-Kickback Statute] or specific intent to commit a violation of the [Anti-Kickback Statute]" to be found to have violated the Act. 42 U.S.C. § 1320a-7b(h).

90. In 2010, Congress amended the Anti-Kickback Statute to clarify that all claims submitted to federal healthcare programs that include items or services "resulting from" Anti-Kickback Statute violations constitute false or fraudulent claims under the FCA. 42 U.S.C. § 1320a–7b(g).

91. While the statute does not define the term "resulting from," the Congressional Record suggests "it was enacted to avert 'legal challenges that sometimes defeat legitimate

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[3] This compliance guided was "intended to assist companies that develop, manufacture, market, and sell pharmaceutical drugs or biological products (pharmaceutical manufacturers) in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the federal health care program…") https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf (last visited May 10, 2021).

[4] https://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_16.htm (last visited on May 10, 2021).

enforcement efforts.'" United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 95 (3d Cir. 2018) (quoting 155 Cong. Rec. at S10853, 2009 WL 3460582).

92. Further, the 2010 amendment was "part of an overall effort . . . 'to strengthen[] whistleblower actions based on medical care kickbacks" as well as "to ensure that all claims resulting from illegal kickbacks are considered false claims." United States ex rel. Bawduniak v. Biogen Idec, Inc., No. 12-CV-10601-IT, 2018 WL 1996829, at *5 (D. Mass. Apr. 27, 2018) (citing Greenfield, 880 F.3d at 96).

93. "[C]ourts have found scienter where one purpose of the remuneration was to induce referrals." United States v. Berkeley Heartlab, Inc., 225 F. Supp. 3d 460, 468 (D.S.C. 2016) (collecting cases); see also OIG Advisory Opinion No. 08-19 (acknowledging the Anti-Kickback Statute "has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals" (emphasis in original)).[5]

94. This condition applies regardless of which entity is submitting the claim. See 31 U.S.C. § 3729(a)(1)(A) (imposing liability not only on a person who presents a false or fraudulent claim, but also on an individual who "causes" the false or fraudulent claim "to be presented"); see also United States ex rel. Wood v. Allergan, 246 F. Supp. 3d 772, 818 (S.D.N.Y. 2017) ("[C]ase law makes clear that the FCA reaches claims rendered false by one party, even if they are submitted to the Government by another downstream entity."), reversed and remanded on other grounds by, 899 F.3d 163 (2d Cir. 2018).

[5] https://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-19.pdf (last visited May 10, 2021)

95. The Anti-Kickback Statute does include a "safe-harbor" provision for referral services, but it clearly indicates the conditions a referral service must meet in order to qualify for this exception. See 42 C.F.R. § 1001.952.

96. Neither Allergan nor Apollo took the steps required to avail themselves of these affirmative defenses, and none of the safe-harbor provisions apply to their illegal conduct.

97. As described below, compliance with the Anti-Kickback Statute is a prerequisite to payment and reimbursement and is material to the government's decision to pay. See 42 U.S.C. § 1320a-7b(g) (explaining that claims resulting from a violation of the Anti-Kickback Statute are false or fraudulent claims under the False Claims Act).

98. In place of making cash payments to induce surgeons to use the LAP-BAND®, the Defendants instead provided lucrative advertising for free on their website, publicity, and inclusion in their free physician locator feature in exchange for use of their product. Here, the free exposure on their website and free inclusion in the physician-locator feature for referrals—and the many benefits that flowed from inclusion—qualify as unlawful remuneration.

II) FEDERAL AND STATE-FUNDED HEALTH INSURANCE PROGRAMS

A. *Medicare*

99. Medicare is a federal program administered through the United States Department of Health and Human Services ("HHS"), insuring people age 65 and older, certain disabled persons, and persons with permanent kidney failure. Medicare Part A covers inpatient hospitalization and extended services for patients after hospital discharge. Medicare Part B provides supplementary medical insurance for medical and other health services, including hospital outpatient services. Adjustable gastric-band devices, including the LAP-BAND® device and the Realize® band, are reimbursable through federal programs like Medicare.

100. The Medicare program works by reimbursing health care providers for the costs of services and ancillary items at fixed rates. Reimbursements are made from the Medicare Trust Fund.

101. The Medicare Trust Fund is supposed to reimburse only for services actually performed, that were medically necessary for the health of the patient, and that were ordered specifically by a physician based on the exercise of appropriate medical judgment and with the best interest of the patient in mind.

102. To become a certified Medicare provider, institutional providers and physicians must enter into Provider Agreements with the Centers for Medicare and Medicaid Services ("CMS"). As part of this agreement, the applicant must sign the following certification before seeking reimbursement from Medicare:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

Form CMS-855a (for institutional providers); see also Form CMS-855I (for Physicians and Non-Physician Practitioners) (agreeing to abide Federal Anti-Kickback Statute along with other federal laws).

103. Applicants represent that they will not "knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and [] will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity." Id.

104. These certifications remained substantially the same, including compliance with the Anti-Kickback Statute, throughout the relevant time period.

105. Additionally, certified Medicare providers must fill out and submit the form CMS-1500, or the electronic equivalent, to make a claim for reimbursement for services rendered.

106. Claims for reimbursement by the provider are generally required to be filed "no later than the close of the period ending 1 calendar year after the date of service."[6] *See* 42 C.F.R. § 424.44; Patient Protection and Affordable Care Act § 6404.

107. In submitting a claim for payment on a form CMS-1500, a provider certifies in part that "the information on this form is true, accurate and complete"; that the provider has "familiarized [itself] with all applicable laws, regulations, and program instructions"; that the claim "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and the [Stark Law]"; and that the services provided were medically necessary. These certifications remained substantially the same during the relevant time period.

108. Published statistics analyzing data from the 2010-2019 timeframe indicate that 6.7 percent of bariatric surgery cases in the United States were covered by Medicare. *See* Kim S, Becerra AZ, Sarran MA, Williams MD, Schimpke SW, Variation in Bariatric Surgery Utilization by State from 2010 to 2019: Analysis of the PearlDiver Mariner Database. SURG OBES RELAT DIS. (2022).

B. ***Medicaid***

109. Medicaid is a program financed jointly by the federal government and the states that provides healthcare coverage for qualified low-income individuals.

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[6] *See also* https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r2140cp.pdf

110. Federal funds are made available to states that provide medical services to eligible recipients. States that choose to participate must comply with certain federal Medicaid requirements and each state administers its own program in accordance with a CMS-approved state plan. 42 U.S.C. § 1396a.

111. The state plan is "a comprehensive written statement submitted by the agency describing the nature and the scope of [the state's] Medicaid program and giving assurance that it will be administered in conformity" with the applicable federal laws and regulations. 42 C.F.R. § 430.10.

112. Providers also use the form CMS-1500, or an electronic equivalent, to submit claims for reimbursement under the Medicaid program. Specifically, related to Medicaid, the form states: "This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws."

113. Like Medicare, participation in Medicaid is also conditioned on compliance with the Anti-Kickback Statute.

114. Accordingly, if a party pays a kickback to induce the implantation of a medical device, as alleged here, the kickback renders the claimant's certification of compliance false because the claim does not comply with the Anti-Kickback Statute.

115. Published statistics analyzing data from the 2010-2019 timeframe indicates that 7.3 percent of U.S. bariatric surgeries were covered by Medicaid. Kim S, Becerra AZ, Sarran MA, Williams MD, Schimpke SW, Variation in Bariatric Surgery Utilization by State from 2010 to 2019: Analysis of the PearlDiver Mariner Database. SURG OBES RELAT DIS. (2022).

C. *Other Government Funded Health Insurance Programs*

116. Tricare is the healthcare system of the U.S. military, designed to maintain the health of active-duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and career military retirees and dependents.

117. Additionally, Tricare providers use the form CMS-1500, or the electronic equivalent, to make a claim for reimbursement for services rendered.

118. Thus, in submitting a claim for payment on a form CMS-1500, a Tricare provider also certifies in part that "the information on this form is true, accurate and complete"; that the provider has "familiarized [itself] with all applicable laws, regulations, and program instructions"; that the claim "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and the [Stark Law]"; and that the services provided were medically necessary."

119. The Veterans Administrations ("VA") provides health care and other benefits to veterans of the military.

120. States also have health care plans to cover state employees. Cities, towns, and other political subdivisions of the States also cover employees through such health care plans.

121. Proper reimbursements under each of these programs is also premised on compliance with federal law, including the Anti-Kickback Statute.

122. These programs reimburse for medically necessary bariatric surgery including LAP-BAND® surgery.

FACTUAL ALLEGATIONS

I) THE LAP-BAND® DEVICE

123. Defendants' adjustable gastric band or LAP-BAND® is an implantable medical device approved by the FDA in 2001 for the treatment of obesity.

124. The LAP-BAND® is implanted in a patient to adjust digestive function in a manner intended to reduce hunger and lessen the amount of food required to feel satisfaction.

125. During the relevant time period, LAP-BAND® implant procedures were conducted throughout the United States.

126. Surgeons were not eligible to independently use the LAP-BAND® device in weight loss surgery until they completed an FDA-mandated training course.

127. Defendants were responsible for providing the requisite training to certify surgeons for implantation.

128. During the relevant time period, the training consisted of a two-day didactic session followed by on-site proctoring by an Allergan designee.

129. A surgeon obtained final certification to perform the LAP-BAND® procedure after successfully completing two proctor-supervised LAP-BAND® implantation procedures.

130. As of the date that the First Amended Complaint was filed, there were approximately 594 facilities approved to do the procedure by CMS, including at least one such facility in each of the above-listed states.

131. While the LAP-BAND® is one surgical option for addressing obesity, it was neither the only nor the favored surgical weight loss option during the relevant times. Alternatives to the LAP-BAND® include the Gastric Bypass and Sleeve Gastrectomy procedures.

132. During the relevant time period, the LAP-BAND® device itself cost hospitals approximately $3,000 apiece.

133. Costs for office visits, LAP-BAND® adjustments, reoperations, upper endoscopies, management of complications, and conversions to other operations add substantially to the initial cost of implanting the device.

134. The initial adjustable gastric band surgery, during the relevant time period averaged approximately $14,000 for most insurers, and about $12,345 for Medicare.

135. The pre-operative phase of LAP-BAND® surgery often entails an extensive amount of testing and other procedures. This preoperative preparatory work that results from a recommendation for LAP-BAND® surgery substantially increases the total cost insurers pay each time a LAP-BAND® procedure is performed. For the first few years after implantation of the LAP-BAND®, frequent post-operative office visits are recommended.

136. The LAP-BAND® adjustment procedures are integral to the wellness of LAP-BAND® patients. The need for such adjustments is the expected result of LAP-BAND® implantation, and they occur at a substantial proportion of LAP-BAND® aftercare visits to providers.

137. Notably, Defendants also sold the adjustment kits necessary for the aforementioned adjustment procedures. LAP-BAND® procedures, therefore, carried the potential to provide the Defendants with a revenue stream long into the future.

138. LAP-BAND® patients frequently have complications, that result in increased doctors' visits, hospitalizations and/or repeat surgery.

139. To be able to choose the best option for their own care, patients must have full and appropriate information about any procedure contemplated, as well as its alternatives.

140. The process by which a bariatric surgeon conveys a recommendation for a specific bariatric surgery is generally a lengthy, multi-stage process. It is not a discreet event whose occurrence can be tracked to a certain, identifiable moment.

141. The process by which a surgeon conveys and then confirms acceptance of a recommendation is the "informed-consent" process, which contains multiple steps.

142. In the United States, a patient always meets the surgeon at least once in an office setting some time prior to the day of surgery. The surgeon is ostensibly responsible for ensuring the patient properly understands the risks, benefits, and alternatives related to the recommended surgery. After the informed-consent process is completed, the doctor attests to having provided the information needed for informed-consent, and the patient attests to receiving that information, and their desire to proceed, with their signatures.

143. On the day of surgery, patients and doctors re-affirm in writing that information necessary to consent to the recommended surgery has been conveyed to the patient, and that the patient desires to proceed with the recommended surgery. The reaffirmation is signed by both parties on the hospital's informed-consent document.

144. During the period in question, 2012 through at least 2018, Medicare only reimbursed LAP-BAND surgery when performed at an inpatient hospital facility.

145. Medicare conditions of participation include the requirement that "[a] properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies."42 C.F.R § 482.51(b)(2); *see also*, 42 C.F.R § 482.24(c)(2)(v). Informed consent generally also requires informing the patient of "the burdens, risks, and expected benefits of all options, including forgoing treatment." AMA Code of Medical Ethics Opinion 2.1.1 (b)(3).

146. The Defendant's entire scheme was set up to circumvent these requirements by (1) pressuring doctors into making their quota of LAP-BAND® referrals, and (2) funneling patients to doctors with an incentive only to provide the LAP-BAND® instead of other surgery, even another gastric band.

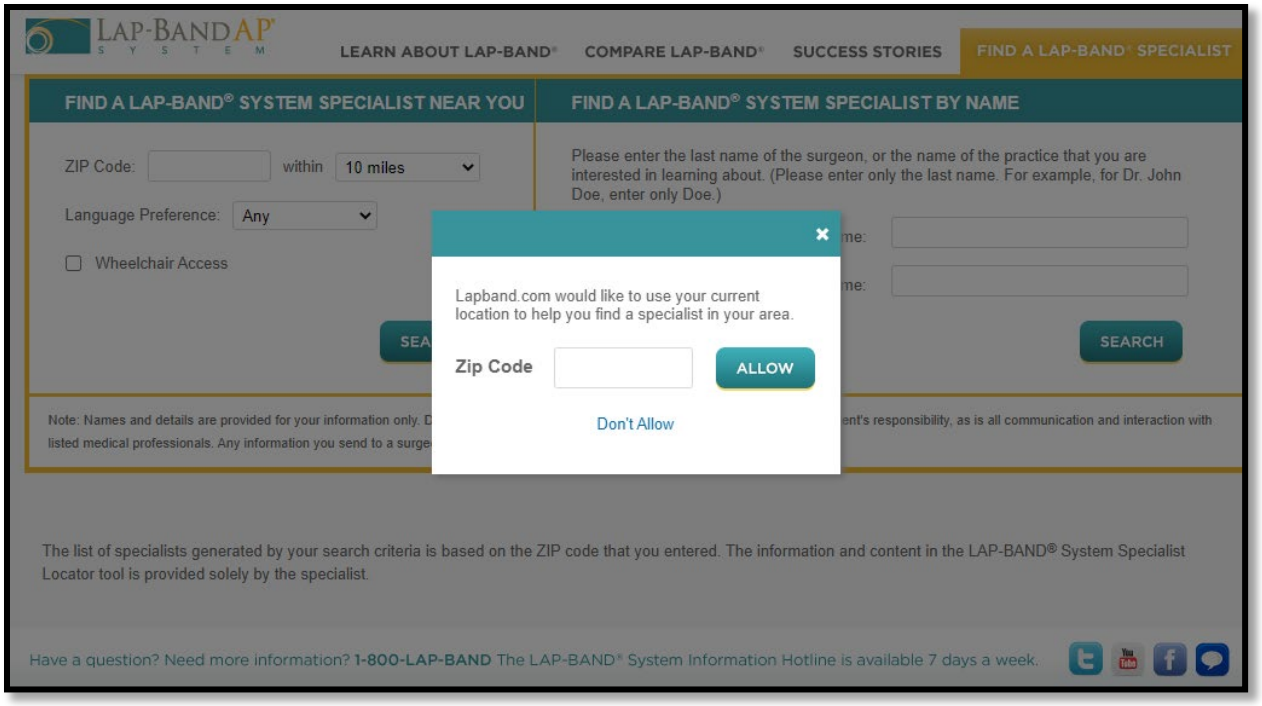
II) DEFENDANTS' OPERATION OF LAPBAND.COM

147. Apollo, and before it, Allergan, operated the www.lapband.com website.

148. The website provided the public with marketing information about Defendants' LAP-BAND® product.

149. Specifically, the website also included a physician locator at relevant times. To operate the physician locator, Defendants maintained and managed a database of qualifying surgeons, who opted in, and were granted inclusion, to Defendants' website.

150. When a potential patient visited www.lapband.com in 2013, for example, a popup window appeared, indicating "Lapband.com would like to use your current location to help you find a specialist in your area" and directing them to insert their zip-code. The locator was available from every webpage. Sometimes a locator window spontaneously popped up without being summoned by a click. In October 2013, the pop-up appeared as follows:



151. Website visitors including potential patients were prompted to input their zip code into Defendants' locator, which responded by providing contact information and qualifications for surgeons.

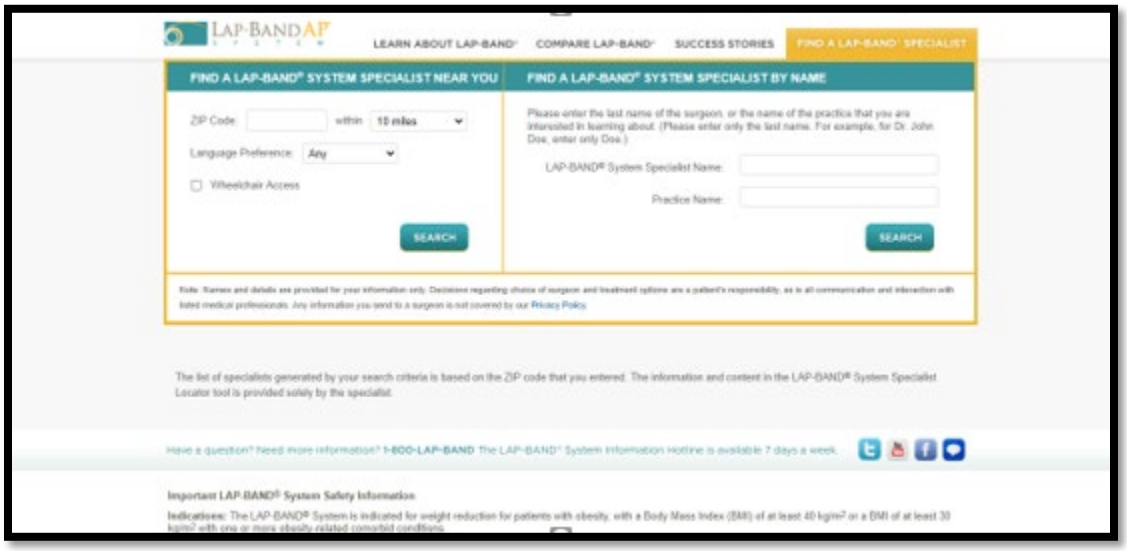
152. Surgeon listings on www.lapband.com provided an active hyperlink to the surgeon's websites, which had positive rippling effects on search optimization for those websites. When potential patients clicked through, the conversions also served to optimize surgeons' own websites. The extra web traffic improved their search ranks, and further increased their virtual exposure to potential patients.

153. The surgeons' information displayed on the locator was provided to Defendants by each physician.

154. In fact, the LAP-BAND® website made this clear at the time, stating: "The list of specialists generated by your search criteria is based on the ZIP code that you entered. *The*

information and content in the LAP-BAND® System Specialist Locator tool is provided solely by the specialist."[7] (emphasis added).

155. The following web capture depicts this notice from October 2013:



156. This notice was also present during the time that Defendant Apollo owned and operated www.lapband.com.

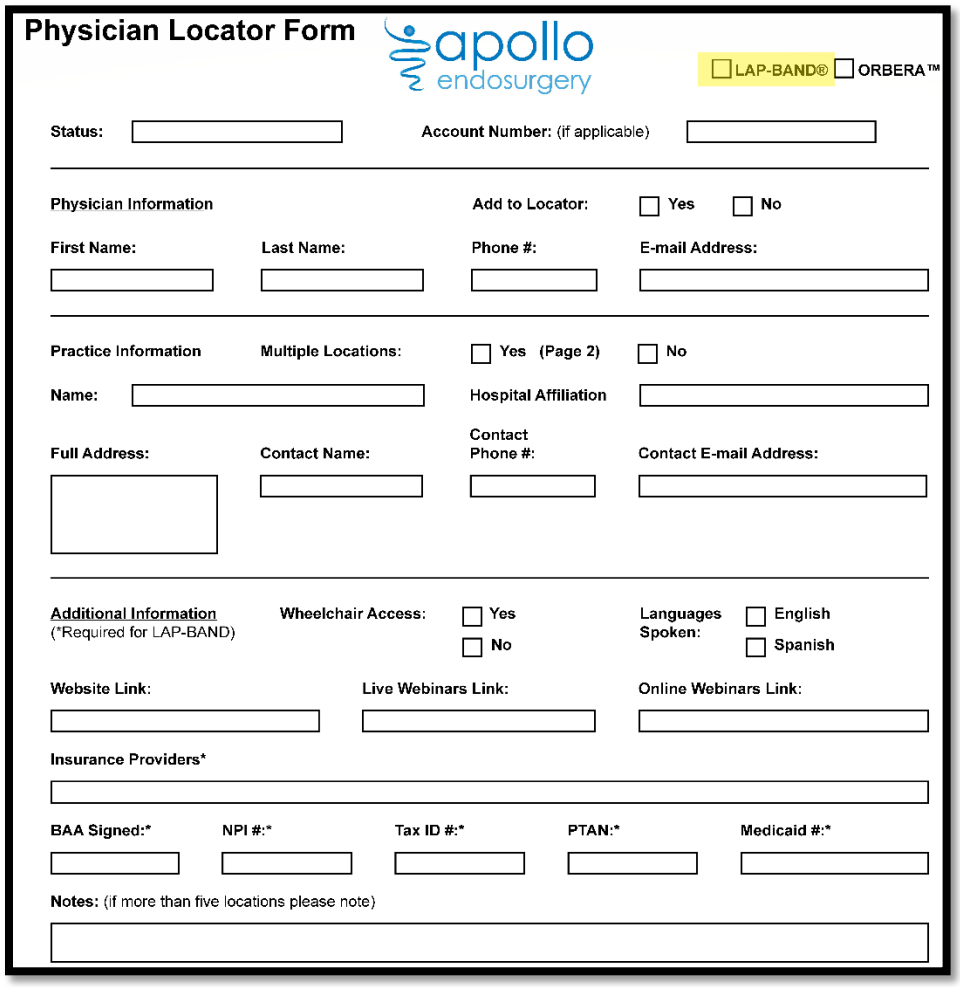
157. In or about 2015, Dr. Fitzer began to perform procedures that required other medical devices made and marketed by Apollo. Among those products were the OverStitch device and the Orbera intragastric balloon.

158. Apollo launched a physician locator for that the Orbera device on its promotional website, www.orbera.com.

159. In or around March 2014, Joe SySantos became account manager at Apollo for the OverStitch and LAP-BAND product lines in the territory that included Dr. Fitzer's hospitals.

[7] As described below, Defendants began referring to physicians on their physician locator tool as "Specialists" following Dr. Fitzer's removal from the locator and mass ejection of bariatric surgeons from the locator in March 2013.

160. When the Orbera was approved by the FDA, SySantos assumed responsibility for it as well. After Dr. Fitzer expressed interest in Orbera training, SySantos emailed Dr. Fitzer a "Physician Locator Form" in October 2016, and instructed him to complete it. A sample of the form is as follows:



Physician Locator Form

apollo endosurgery

☐ LAP-BAND® ☐ ORBERA™

Status: _____ **Account Number:** (if applicable) _____

Physician Information **Add to Locator:** ☐ Yes ☐ No

First Name: _____ **Last Name:** _____ **Phone #:** _____ **E-mail Address:** _____

Practice Information **Multiple Locations:** ☐ Yes (Page 2) ☐ No

Name: _____ **Hospital Affiliation** _____

Full Address: _____ **Contact Name:** _____ **Contact Phone #:** _____ **Contact E-mail Address:** _____

Additional Information (*Required for LAP-BAND) **Wheelchair Access:** ☐ Yes ☐ No **Languages Spoken:** ☐ English ☐ Spanish

Website Link: _____ **Live Webinars Link:** _____ **Online Webinars Link:** _____

Insurance Providers* _____

BAA Signed:* _____ **NPI #:*** _____ **Tax ID #:*** _____ **PTAN:*** _____ **Medicaid #:*** _____

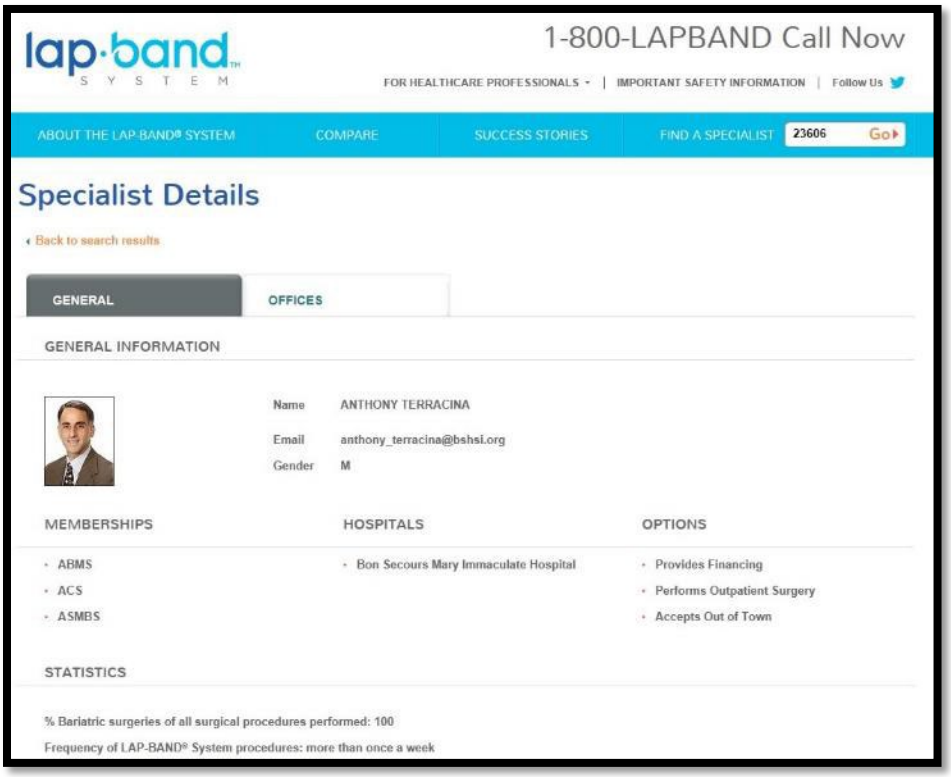
Notes: (if more than five locations please note) _____

161. Joe SySantos told Dr. Fitzer that full completion of the form was required to obtain a locator listing for Orbera.

162. The form's checkboxes indicated that it is the same form used to register surgeons for the LAP-BAND® locator, as Relator highlighted in the image in paragraph 160.

163. Dr. Fitzer was first asked by Allergan to complete a similar form to obtain his LAP-BAND® locator listing in 2007 and 2012.

164. In or about 2014, the LAP-BAND® physician locator profiles were modified to include color photos and practice-specific statistics. The following is an example of a portion of the physician's profile page on www.lapband.com as it appeared in November of 2014:



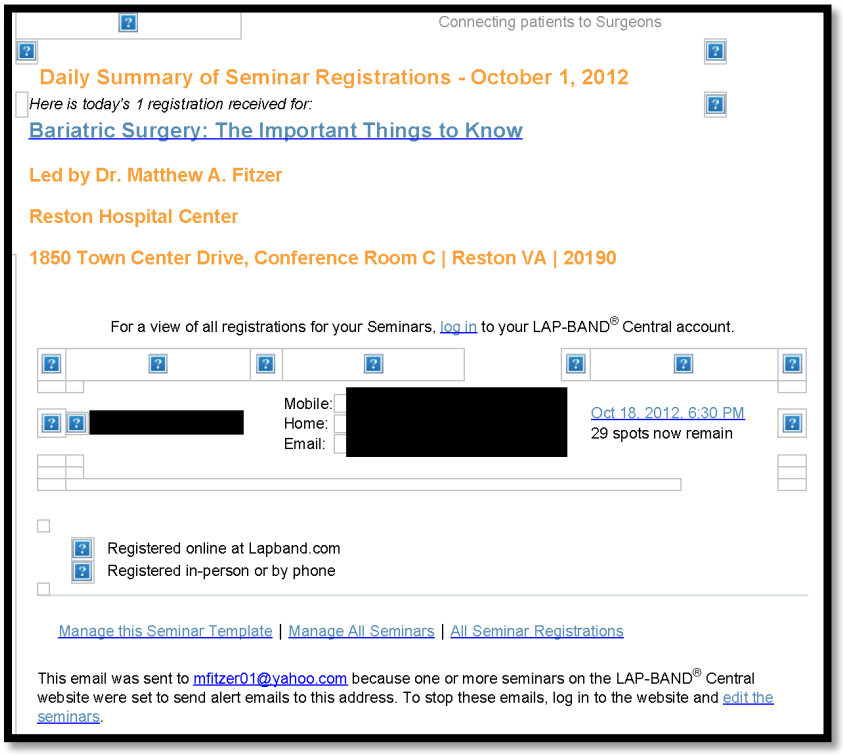
165. The statistics in this profile are not generally available from another source besides the physician.

166. Until approximately March 2013, Defendant Allergan also listed up-to-date seminar schedule information for any doctor on its site.

167. This sophisticated seminar sign-up system was another useful benefit for the surgeons on the locator. The seminar schedule was listed on a surgeon's profile. The surgeon

provided details such as seminar dates the maximum number of people, and location, and then patients were able to click on them and input their information.

168. Defendant Allergan emailed surgeons a "Daily Summary of Seminar Registrations" from a no-reply@allegan.com account, alerting the physician of registrations received by Allergan for the surgeon's seminar. The summary included the name and contact information for the individuals registered. By way of example, Dr. Fitzer received one of these emails in 2012:


Connecting patients to Surgeons

Daily Summary of Seminar Registrations - October 1, 2012

Here is today's 1 registration received for:

Bariatric Surgery: The Important Things to Know

Led by Dr. Matthew A. Fitzer

Reston Hospital Center

1850 Town Center Drive, Conference Room C | Reston VA | 20190

For a view of all registrations for your Seminars, log in to your LAP-BAND® Central account.

[redacted]

Mobile: [redacted]
Home:
Email:

Oct 18, 2012, 6:30 PM
29 spots now remain

Registered online at Lapband.com
Registered in-person or by phone

Manage this Seminar Template | Manage All Seminars | All Seminar Registrations

This email was sent to mfitzer01@yahoo.com because one or more seminars on the LAP-BAND® Central website were set to send alert emails to this address. To stop these emails, log in to the website and edit the seminars.

169. The email stated in part: "For a view of all registrations for your Seminars, log in to your LAP-BAND® Central account."

170. LAP-BAND® Central accounts were a convenient means by which physicians could complete tasks related to managing a LAP-BAND surgery practice. Surgeons accessed their LAP-BAND® Central accounts by logging in on www.lapbandcentral.com.

171. Once logged in, physicians could access various features. Among them were training materials, including videos; an online store where LAP-BAND adjustment equipment

could be ordered; and a dashboard, through which surgeons could view update seminar information, etc.

172. On the basis of his Orbera training, Dr. Fitzer was later granted a limited www.lapbandcentral.com account with access limited to Orbera-related features in or about November 2016. This account provided a "referral dashboard" where referrals received from the Orbera locator website were listed, including the referral date, the name of the referred patient, their telephone number, their email, the office they were referred to, and the source of the referral (e.g., Orbera.com in this instance)." Defendants did not restore Dr. Fitzer's access to the LAP-BAND functionality or his www.lapband.com locator listing when granting him access to www.lapbandcentral.com.

173. The above notices, postings, and communications make clear that physicians were active, knowing participants in the process of securing a listing on the locators operated by the Defendants.

174. During the relevant time period, Defendants marketed the website extensively, causing it to become a popular way for patients throughout the United States to find their weight-loss surgeons.

175. By way of example, Defendants ran commercials expressly directing the viewer to "[g]o to www.lapband.com [t]o find a Specialist in your area." This commercial, like most of Defendants' promotions, had the visible goal of sending patients to the locator. The surgeons on the locator reaped the benefits of the advertising and paid nothing for it.

176. In Dr. Fitzer's personal experience, the LAP-BAND® physician locator was widely known among bariatric surgeons. Dr. Fitzer knew this through discussions he had with other bariatric surgeons about practice management.

177. Dr. Fitzer's former office suitemate once attributed his entire practice to referrals from www.lapband.com.

178. Www.lapband.com had a very polished and professional design, and Defendants obviously had invested substantial time and money on it. It enjoyed a very high search rank on popular search engines like Google.

179. Defendants also spent lavishly on search-engine advertising to increase traffic to the site and maintain its popularity. By way of example, the first ad below appeared when Relator searched "lap band" on Yahoo in February 2014, and the second image appeared when Relator searched "lap band" on Google in May 2013:

180. Defendants optimized the website and bought search-engine advertising spots to increase its online traffic.

181. The General Manager of the Obesity Business Department at Allergan, Jim Caggiano, estimated that the marketing budget reached $60 million. According to SEC filings, Allergan spent $171.4 million on advertising alone in 2010.

182. Marketing included Allergan's website www.lapband.com.

183. The website provided constant exposure and flow of business to the included surgeons. It represented one of the most effective methods of marketing for them, and therefore, website access and inclusion was greatly valuable to the included weight-loss surgeons.

184. Alternative forms of web-based marketing were costly in time and effort, and they were generally less effective than inclusion on www.lapband.com during this time.

185. By way of example, between March 1, 2013 and March 1, 2015, Dr. Fitzer spent approximately $202,000 on Google ads, approximately $30,000 on Bing ads, and approximately another $28,000 on search engine optimization for his practice website. In monitoring his own ads, Dr. Fitzer recognized that www.lapband.com was a fierce competitor in the click-ad space.

186. Between March 1, 2013 and March 1, 2015, at least 50% of Dr. Fitzer's patients found him through online search ads.

187. It was common practice for websites to charge surgeons for inclusion on their platforms. In Dr. Fitzer's experience, a year of exposure typically cost thousands of dollars.

188. By way of example, Dr. Fitzer paid $6,000 to be listed on yourbariatricsurgeryguide.com for a single year's exposure.

189. Dr. Fitzer also paid $3,500 to be listed on locateadoc.com for a single year's membership in their locator during the relevant time period.

190. During the relevant times, Dr. Fitzer paid $198 per month to be included in the Obesityhelp.com surgeon locator.

191. Unlike Defendants, the companies behind these paid websites were not pursuing other financial goals in the healthcare marketplace as none of them were associated with the manufacturing of any product and had no financial stake in the outcome of referrals they made.

192. Thus, online advertising—especially well trafficked advertising—was and is costly and of considerable value to bariatric surgeons. Advertising was a necessity for a bariatric surgery practice.

III) DR. FITZER'S INTERACTIONS WITH LAPBAND.COM

A. *Dr. Fitzer Registers for www.Lapband.com.*

193. In fall 2006, Dr. Fitzer completed LAP-BAND® certification and training.

194. His then LAP-BAND® account manager provided him with a form requesting various contact information. The account manager indicated the completed form had to be returned to obtain a www.lapband.com locator listing. Dr. Fitzer returned the form and obtained a listing.

195. This form appeared to be used as routine business and was not tailored to Relator.

196. In February 2012, Dr. Fitzer moved to Northern Virginia to start his own bariatric surgery practice.

197. Having just arrived in a new market, Dr. Fitzer was looking to increase his market presence.

198. Dr. Fitzer attended a practice development seminar in February 2012. The presentation stressed that inclusion in the www.lapband.com referral database was a very valuable promotional resource that should be requested by qualified surgeons. They described it as a "must-have." Dr. Fitzer was told (and knew from his past experience) that inclusion on the website was available for surgeons who were trained to perform the LAP-BAND® procedure, and that he should contact the company if he wished to be included.

199. At the time, the website was a popular and easy way for potential patients to find a surgeon in their area who performed bariatric surgery.

200. As a professional bariatric surgeon who was trained in and willing to implant the LAP-BAND®, Dr. Fitzer had a natural interest in consulting with patients who were considering having the LAP-BAND® or any other bariatric procedure.

201. On March 6, 2012, Dr. Fitzer met with Allergan Account Manager Meagan McDaries.

202. Dr. Fitzer asked to be included in the database for referrals by www.lapband.com.

203. Rather than simply signing Dr. Fitzer up, Ms. McDaries instead probed into his decision-making process with regard to recommending a LAP-BAND® implant as opposed to other kinds of surgery.

204. She asked what would make him decide to do a LAP-BAND® procedure and in what percentage of these cases he would be likely to do a LAP-BAND® implant.

205. Ms. McDaries encouraged Dr. Fitzer to track leads he received from the LAP-BAND® website and provided Dr. Fitzer with a "LAP-BAND Patient Log" spreadsheet to do so. She indicated that the patient tracker was provided for free to all LAP-BAND® surgeons.

206. Tracking leads generated by the website allowed surgeons like Dr. Fitzer to acknowledge the true value of inclusion on the locator.

207. Ms. McDaries informed Dr. Fitzer that he would be granted access to the website and therefore added to the physician locator.

208. Ms. McDaries encouraged Dr. Dan Turgeon, a general surgeon of Dr. Fitzer's acquaintance, to register for LAP-BAND® training. She provided a workshop application, which included a question for the surgeon, asking that the surgeon provide an estimate of the annual number of LAP-BAND® System cases they will perform in a year.

209. There was no obvious training-related reason for Allergan to want that information. The application indicated that a surgeon-trainee only needed to complete two proctored cases to become eligible to perform cases independently.

210. The application also appeared to give a surgeon's sales representative veto power over a surgeon's ability to obtain LAP-BAND training by requiring the representative to provide a signature approving the surgeon's attendance.

B. ***Defendants Pressure Dr. Fitzer to Use LAP-BAND®.***

211. Ms. McDaries came to Dr. Fitzer's Reston office a few days after the lunch meeting. She provided him with a surgeon locator information form similar to the form identified in in paragraph 160. After Dr. Fitzer completed the form and returned it to her, she sat down and entered the data into her laptop, double-checking the information verbally as she went.

212. After Dr. Fitzer was told that he would be listed on the website in 2012, Dr. Fitzer was subjected to a roughly two-month wait prior to appearing on www.lapband.com.

213. There was no technical reason why such an approval should not occur instantaneously, and Dr. Fitzer was given no substantive reason why the delay occurred.

214. The only other surgeon listed on the website in Dr. Fitzer's zip code at that time was Dr. Robert Pinnar, who was a LAP-BAND® only surgeon, meaning he only offered the LAP-BAND® as a surgical option to treat obesity.

215. Any referrals made by Allergan to a LAP-BAND® only surgeon would likely result in the sale of a LAP-BAND® because they would not be able to perform any of the other recommended procedures to treat obesity and would also be unlikely to recommend those alternatives, including the competing medical device, the Realize® band, which required separate certification.

216. Dr. Fitzer was added in June of 2012. He felt the impact of his inclusion in the locator immediately with an increase in inquiries to, and patient traffic through, his office.

217. However, Dr. Fitzer also experienced problematic and unexplained gaps in service with his account.

218. Dr. Fitzer has reason to believe that these gaps in service resulted from Allergan's dissatisfaction with his LAP-BAND® productivity.

219. Dr. Fitzer also had reason to believe Allergan monitored the number of LAP-BAND® procedures that surgeons on its site conducted and gave preferential treatment to LAP-BAND® only doctors by having their advertising display more often to consumers looking at the site. Further, Dr. Fitzer noticed that in some cases the listings did not sort according to distance, nor were surgeons listed alphabetically.

220. On or about September of 2012, Dr. Fitzer found that he could not update his informational seminar schedule in Allergan's referral base because he was "locked out" of his www.lapband.com account.[8] To www.lapband.com website visitors, it would seem that Dr. Fitzer was not in business. He asked Allergan to restore his access.

221. It took multiple calls and emails and additional time before Allergan restored Dr. Fitzer's access to his account. Allergan was willing to discuss the reasons for the account outage by email.

222. Dr. Fitzer was aware that other surgeons, including his LAP-BAND® only suitemate, continued to schedule seminars and conduct business as usual on the website while he was unable to do so.

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[8] Allergan later discontinued listing such seminars on its website, and instead provided links directly to surgeons' own websites where the surgeons may list such seminars.

223. To Dr. Fitzer's knowledge, LAP-BAND® only surgeons did not experience the same lockouts as Dr. Fitzer.

224. The message to Dr. Fitzer or any bariatric surgeon was unmistakable: to keep access to referrals and other valuable benefits from Allergan's physician locator and access to its website marketing capabilities, surgeons should encourage LAP-BAND® procedures over any other procedures. This of course would deny patients of a real opportunity to choose another procedure as part of a full informed consent process.

225. In addition, by favoring the LAP-BAND® only surgeons, Defendants not only increased orders of their medical device, but Defendants also incentivized other bariatric surgeons to increase their recommendations of the medical device. If surgeons who were cable of doing the other procedures wanted to compete in the marketplace for patients, they had to refer the LAP-BAND®.

226. Defendants' offer of financial incentives to surgeons to recommend their product to patients rather than discuss all alternatives perverts the informed consent process, which is central to medical ethics and a condition of participation for Medicare and other government programs. *See* 42 C.F.R. §. 482.51(b)(2); C.F.R. §482.24(c)(2)(v).

C. *Allergan Removed Dr. Fitzer From Its Website Database Based On LAP-BAND® Sales Quota.*

227. Dr. Fitzer was denied website access and was removed from the physician locator in March of 2013.

228. Dr. Fitzer first learned that he had been removed while attempting to order LAP-BAND® related medical supplies from Allergan's website.

229. Dr. Fitzer assumed that it was one of the usual periodic disruptions.

230. On March 24, 2013, he sent an email to Jeff Stitely, his Allergan Account Manager:

> Jeff,
>
> I just was attempting to access my Lapbandcentral account to order some lap band needles, etc. and I found that my account has been deleted.
>
> I then checked and noted that it was deleted as well from the patient side, meaning that a search in my office's zip code only produced other surgeons.
>
> I would like to be contacted asap about getting my listing up, and getting those needles.
>
> Thanks for your immediate attention to this.

231. Mr. Stitely replied on the same day with no indication that anything was wrong:

> Good Evening Dr. Fitzer,
>
> Please see the newest ordering catalog that has the direct phone number for ordering supplies. This will allow you to at least order needles ASAP. There are several reasons that the account may not be allowing you access. I will investigate this tomorrow and update you with my findings. Have a good evening.
>
> Jeff

232. In his response, Dr. Fitzer was clear that his concern was being able to obtain access to, and referrals from, the www.lapband.com account, explaining in part:

> By all means, investigate the account's deletion. The reasons for the disappearance of my account, however, are not of primary importance to me, and I do not want any investigation into that to delay what is of great importance to me - - turning on the account again. The turning on of the account is what needs to happen tomorrow.

233. Allergan never turned on the account, and it remains closed as of this filing.

234. Mr. Stitely wrote on March 26, 2013, that he had, "gotten clarification about the account" and scheduled a call with Dr. Fitzer to discuss the matter on March 26, 2013.

235. On or about March 26, 2013, Dr. Fitzer spoke with Mr. Stitely by telephone.

236. Mr. Stitely stated that the reason Dr. Fitzer had been removed from the list of surgeons on the website was because Dr. Fitzer had not conducted at least 40 LAP-BAND® procedures in a year.

237. Mr. Stitely informed Dr. Fitzer that Allergan had a new policy to condition inclusion in the referral database on the basis of a surgeon conducting forty (40) LAP-BAND® implant procedures in a year. This was the first time in his career that Dr. Fitzer had heard of such a quota, and he was shocked.

238. Mr. Stitely had been Dr. Fitzer's Account Manager since December of 2012 and had at least two years of previous experience marketing the LAP-BAND®.

239. Dr. Fitzer attempted to find help getting reinstated higher in the Allergan chain of command.

240. Dr. Fitzer contacted Paul Hickey, the Regional Director, who referred Dr. Fitzer to Mark Didio, Allergan's Vice President of Sales and Mr. Hickey's supervisor.

241. Mr. Didio's territory included North America.

242. Dr. Fitzer emailed Mr. Didio on March 27, 2013, explaining in part:

> Jeff Stitely, my local rep, explained to me that my account was deleted because it is Allergan's policy now to exclude physicians who don't do 40 bands per year. I explained to him that **when a medical device maker decides to selectively favor only high-referring physician practices with the benefits of their paid advertising and web-related services, it is an unambiguous violation of federal law**. Specifically, I am referring to Stark and Anti-Kickback here.

(emphasis added).

243. However, Dr. Fitzer was clear that he wanted to resolve the issue amicably if possible.

> Personally, I would prefer a more constructive resolution of this situation. What I would like is prompt reinstatement of my account and entry under surgeon-search. I believe it makes sense for Allergan to do that. The fact is: I am the one surgeon in the area who accepts band patients from other surgeons, including out-of-country bands. This week, in fact, I saw 4 new LAP-BAND consults seeking to initiate follow-up for band they already have.

244. Dr. Fitzer closed his email with a request for a written explanation of the Allergan policy if he was not reinstated:

> If you feel immediate reinstatement won't be possible, a written explanation of Allergan's policy of excluding low-referring surgeons from its referral database would suffice.

245. Allergan did not reinstate him nor has the company provided a written explanation.

246. Notably, this was the first time Allergan had ever refused to discuss specific concerns about his www.lapband.com account in writing.

247. Allergan had previously been willing to discuss reasons for referral-service outages in writing.

248. On the evening of March 28, 2013, Dr. Fitzer spoke with Mr. Didio by telephone.

249. Mr. Didio confirmed that forty (40) LAP-BAND® procedures were required for referrals from www.lapband.com.

250. Dr. Fitzer told Mr. Didio during this phone call that Defendant Allergan was committing healthcare fraud.

251. Further, Dr. Fitzer attempted to explain to Mr. Didio how Allergan's conduct violated the Anti-Kickback Statute. A debate ensued and Dr. Fitzer cited the example of a drug-branded pen, telling Mr. Didio that companies like Allergan were not even allowed to give away pens anymore.

252. Dr. Fitzer further explained that the advertising benefits with which Allergan was now rewarding sales were many orders of magnitude more valuable than a pen.

253. Dr. Fitzer told Mr. Didio that the new policy was obviously bribery and was contrary to the Anti-Kickback Statute.

254. Dr. Fitzer also told Mr. Didio that given what he read in the newspapers—the LAP-BAND® device's rapid market decline, the tentative announcement of a possible sale—it was obvious what Allergan was up to with the quota. It was a ploy to prop up the LAP-BAND® long enough to sell it, to avoid the impending write-down.

255. Mr. Didio did not deny it. His response to that accusation was silence.

256. Dr. Fitzer told Mr. Didio that if he could not dissuade him from proceeding with the scheme, which seemed to be the case, then he would be contacting a lawyer.

257. In the course of the conversation, Dr. Fitzer mentioned qui tam attorney and the US Attorney's office as another possibility. Mr. Didio indicated that he needed to discuss the matter with Allergan's CEO.

258. At the closing of the call, Dr. Fitzer ask Mr. Didio for documentation of the quota system in writing, which Mr. Didio refused.

259. When Dr. Fitzer asked why Mr. Didio refused to provide him with the quota policy in writing, Mr. Didio said it was because Dr. Fitzer had talked about involving lawyers.

260. Mr. Didio claimed during telephone conversation with Dr. Fitzer that the requirement of forty LAP-BAND® procedures was related to "quality," but did not explain how this requirement was related to "quality" as it is clearly only a measure of quantity.

261. Dr. Fitzer disputed Mr. Didio's sham explanation during this call.

262. Notably, the company has never cited a specific issue with regard to Dr. Fitzer's work or his patient outcomes as a reason to justify its action as based on "quality."

263. Further, Defendants' decision not to include surgeons from some of the most prestigious medical institutions in the world, such as Mayo Clinic, The Cleveland Clinic, and John Hopkins University, was another indicator that the quality justifications were false.

264. If Allergan had a concern that low-referring LAP-BAND® surgeons produce inadequate outcomes, there are established channels to address that problem, including providing additional training and petitioning the FDA to change the credentialing procedures for surgeons.

265. At no time did Mr. Stitely, Mr. Didio, or any other Allegan official contradict the substance of the emails Dr. Fitzer sent regarding the reasons given to remove him from the database of surgeons referred by www.lapband.com.

266. Indeed, Dr. Fitzer learned of the forty (40) LAP-BAND® per year requirement to obtain referrals as a result of his telephone conversations with both Mr. Stitely and Mr. Didio.

267. Mr. Stitely and Mr. Didio both confirmed the requirement that surgeons conduct forty LAP-BAND® implant procedures per year to be listed on the website and receive referrals.

268. At the time Defendant Allergan removed Dr. Fitzer from www.lapband.com and the locator, to Dr. Fitzer's knowledge, he had performed more successful bariatric surgeries than the majority of the surgeons that were permitted to remain on that database available for referral.

269. Nonetheless, Mr. Didio maintained that forty (40) implant procedures per year were required for Dr. Fitzer to be listed on the website and to receive referrals from the www.lapband.com website.

270. Dr. Fitzer subsequently learned of other bariatric surgeons who did not fulfill a forty (40) LAP-BAND® per year quota, and who were removed from the LAP-BAND® physician locator at approximately the same time as his listing was.

271. Examining the www.lapband.com locator results in other markets allowed Dr. Fitzer to conclude that his expulsion did indeed reflect a nationwide phenomenon.

272. According to Dr. Fitzer's analysis of American Society for Metabolic and Bariatric Surgery, the physician locator only included approximately 21% of the surgeons who could perform the procedure.

273. While Defendant Allergan used a forty (40) LAP-BANDS® per year quota that excluded qualified surgeons from their physician locator, Allergan was still willing to sell

individual LAP-BANDs® to be implanted by those surgeons who failed to meet the criteria for inclusion on their website for referral privileges. Defendant Allergan's claimed concern for "quality" did not cause it to reject orders or implantation from, or to report to any agency, those physicians it excluded from its site.

274. Following Dr. Fitzer's removal from the physician locator, Defendant Allergan began referring to the surgeons listed on www.lapband.com as "Specialists."

275. Defendant Allergan failed to explain publicly why these listed surgeons qualified as "Specialists" and to Relator's knowledge, had no independent authority to create credentialing policy. The "Specialist" designations can only be understood as a marketing tool, another benefit awarded to surgeons for good LAP-BAND® usage. Defendants used obviously reassuring titles for which they had no authority to bestow.

276. The Defendants have acted to conceal information from patients about some of the best surgical practices in the world.

277. To patients in need of LAP-BAND® care, Defendants' locator policy would be an impediment to obtaining that care. When they searched for local bariatric practices on www.lapband.com, they would find significantly fewer options.

278. As a result, patients in need of care who trusted the Defendants' www.lapband.com physician finder—seemingly a good resource for finding LAP-BAND® —would often have to travel much further than necessary for care, or they might have been compelled to forego care altogether.

IV) ALLERGAN IMPLEMENTED AN ILLEGAL QUOTA DURING RAPID DECLINE OF LAP-BAND® DEVICE SALES.

279. By 2012, annual LAP-BAND® sales revenue had fallen to $160 million from the $296 million in 2008.[9]

280. Gastric band procedures had been the most popular weight-loss procedure in 2008, but by 2013, they comprised only 14% of the U.S. bariatric surgery market. Gastric-band market share fell to 5.7% by 2015, and it was just 3.4% by 2016.

281. With sales plummeting nearly 50% in the span of four years, Allergan understood that the survival of the LAP-BAND® business was threatened.

282. In or about 2012 and 2013, Allergan took actions that reflected tacit acknowledgement that the LAP-BAND's prospects were bleak. Primarily, they slashed LAP-BAND® related business expenses. R&D work on the EasyBand®, a remote-controlled version of the LAP-BAND®, was terminated, as was an effort to obtain FDA approval to use the LAP-BAND® in teenagers. In 2013, they scrapped the LAP-BAND TOTAL CARE ™ quality program and their patient support website, despite having just touted both programs to the FDA in 2012.

283. As the LAP-BAND® device's reputation was imploding, the device's clinical performance was pilloried by leading bariatric surgeon-scientists.

284. Michel Gagne, a preeminent thought leader in bariatric surgery, discussed adjustable gastric banding in a July 2012:

> "It's a complete disaster, when you think that banding in the United States, based on the BOLD data, is the second-most common procedure," said Dr. Gagner. "Europeans are abandoning banding and the Americans are not getting the message. This abandonment

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[9] Tess Stynes, "Allergan Agrees to Sell Lap-Band Business" *The Wall Street Journal* (Oct. 29, 2013), *available at* https://www.wsj.com/articles/SB10001424052702303471004579165961441181356 (last visited Oct. 5, 2021).

> that we see in Europe — we are probably going to see this in the next few years in the United States."

285. Other contemporary thought leaders criticized the LAP-BAND® in similarly stark terms. In a 2013 editorial, Eric Demaria, a past president of the ASMBS bariatric professional society, had pointed criticism for the LAP-BAND® and, specifically, Allergan:

> Combining the frequent need for reoperation and explantation with the failure of the device to consistently provide adequate weight loss has led to the AGB procedure's dramatic fall from popularity.
>
> …
>
> **Let's not mince words here: the band flourished, and is now dying, as a result of corporate greed. The Lap-Band manufacturer did not listen to experienced bariatric surgeons** who advised doing the necessary studies to determine which subgroups of the broad spectrum of morbidly obese patients were likely to achieve good weight loss.
>
> …
>
> The fall of the AGB into disfavor was predicted by many, and yet we should take no pleasure in being proved correct. Widespread application of yet another bariatric surgical procedure that becomes discredited repeats the history of other failed bariatric procedures, including…

(emphasis added).

286. Walter Pories, another highly respected leader in bariatric surgery and past president of the ASMBS professional society, was equally blunt in another editorial:

> How long does it take to abandon an operation that does not work? Although the high failure rates of LAGB were evident even a decade ago, thousands of patients continued to be subjected to this procedure in the United States alone: 9270 in 2003; 96,800 in 2008; 27,630 in 2011; and 15,523 in 2013 [l]. Many are still being done today. How many of these patients were warned that the operation has a high failure rate that would probably require at least one more operation to secure the benefits of surgery? How many were warned that this revision would be more dangerous than a primary intervention?

287. That the LAP-BAND® product line was in trouble was apparent within the business community. According to Business Insider:

> You don't need a crystal ball to see that **Allergan** (AGN) has run into trouble on its Lap-Band stomach shrinking device: Its obesity intervention revenues sank 12 percent to $54.4 million in Q2 2011, making it an almost negligible part of the Botox-maker's business.
>
> Allergan has already discontinued one of its gastric banding devices, the EasyBand, and there are reasons to believe the company might consider axing the Lap-Band, too: It keeps killing and injuring people.[10]

288. By October, 2012, Allergan CEO Davit Pyott had announced his intention to sell the entire product line.[11]

289. In January 2013, Mr. Pyott indicated the LAP-BAND® sale would "come to pass" in Q1 2013.[12]

290. By February 2013, the company indicated that there may be "a disposal loss" related to assets for sale.[13]

291. Sale to Apollo was finalized in December 2013.

V) THE REALIZE® BAND

292. The Realize® band, the one direct competitor of the LAP-BAND® device, also encroached on LAP-BAND® market share at this time.

293. In or about 2007, the FDA approved the Realize® band, which was manufactured and sold by Ethicon Endo-Surgery (Ethicon).[14]

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[10] Jim Edwards, *The Maker Of Stomach Lap-Bands May Be Axing The Product Because It Keeps Killing People*, Business Insider, Sept. 8, 2011.
[11] Andrew Pollack, *As Sales Fall, Allergan Seeks a Buyer for Lap-Band*, N.Y. Times, Oct. 30, 2012).
[12] Ryan Flinn, *Allergan Seeks Sale of Obesity Business by First Quarter*, Bloomberg, Jan. 8, 2013.
[13] Chad Terhune, *Allergan looks to find buyer for Lap-Band unit in first half of 2013*, The Los Angeles Times, Feb. 5, 2013.
[14] BioSpace, FDA Approves Ethicon Endo-Surgery, Inc.'s REALIZE™ Adjustable Gastric Band for Morbid Obesity (Sep. 28, 2007), https://www.biospace.com/article/releases/fda-approves-ethicon-endo-surgery-inc-s-realize-tm-adjustable-gastric-band-for-morbid-obesity-/(last accessed on October 5, 2021).

294. The Realize® band is the only adjustable gastric band other than LAP-BAND® to be approved by the FDA.

295. The Realize® band also had a surgeon locator tool on their flagship website, www.Realize.com.

296. However, unlike www.lapband.com, the website expressly stated the criteria for surgeon inclusion and did **not** condition inclusion on the use of their own Realize® band, or any other specific device.

297. In comparison, Defendants failed to make any disclosure of criteria for inclusion on their website until 2015. Their criteria, when they finally appeared, only counted cases using their LAP-BAND® product toward the volume requirement. It was therefore literally a sales quota.

298. There is no substantial difference between procedures using the Realize® band and the LAP-BAND®. Placement of the two bands is procedurally very similar, at least with regard to the important steps.

299. Crucially, however, the FDA imposed a separate training requirement for each device.

300. For a surgeon to become eligible to perform the procedure using a LAP-BAND® device, they had to complete a two-day LAP-BAND®-specific didactic course.

301. After completing the didactic course, the surgeon was eligible for LAP-BAND® proctoring. Allergan had the responsibility to designate surgeons to serve as LAP-BAND® proctors, who trained other surgeons. A surgeon who had completed the didactic course would schedule a visit by a LAP-BAND® proctor, and they were also responsible for scheduling at least two LAP-BAND® procedures for the day of the visit. When the cases were successfully

completed, the proctor signed off on the surgeon's completion of the LAP-BAND® training requirements, and the surgeon would receive the requisite LAP-BAND® certification.

302. Ethicon oversaw a structurally similar, but distinct, training regime that could certify surgeons to use the Realize® device.

303. Training was non-transferrable between devices. Completion of LAP-BAND® training ***did not*** permit surgeons to use the Realize® band, nor did Realize® training permit surgeons to use the LAP-BAND®.

304. Accordingly, some surgeons who were certified to implant one device were not eligible to use the other. Because the LAP-BAND® obtained FDA approval six years earlier than the Realize®, there were many trained LAP-BAND® surgeons in America by the time the Realize® appeared on the market.

305. In Dr. Fitzer's case, he delayed Realize® certification until 2012. It had been available since 2007.

306. In order to be eligible to implant the Realize® band, physicians were required to attend a professional education seminar by Ethicon and receive a Certificate of Completion.

307. Dr. Fitzer attended the Realize® training and received the Certificate of Completion.

308. In Dr. Fitzer's experience, it was (and remains) standard practice for bariatric surgeons to list all of their certifications and qualifications in promotion materials, including on their websites and/or social media.

VI) DEFENDANT ALLERGAN WAS SUBJECT TO A CIA WHEN IT IMPLEMENTED A VOLUME-BASED QUOTA.

309. In 2010, Defendant Allergan was subject to a Corporate Integrity Agreement (CIA) with the HHS-OIG after pleading guilty and paying $600 million to resolve its criminal and civil liability arising from the company's unlawful promotion of its Botox® product.[15]

310. Two of the complaints that lead to the CIA involved AKS claims.[16]

311. The CIA Allergan entered into with the HHS-OIG in 2010 provided in part that all officers, directors, and U.S. employees of Allergan or any Allergan Affiliate were "Covered Persons." CIA at p. 2.

312. The CIA defined "Relevant Covered Persons" as "Covered Persons whose job responsibilities related to Promotional Function or Product Related Functions." Id. at p. 3.

313. "Promotional Functions" included: "(a) the selling, detailing, marketing, advertising, promotion, or branding of Government Reimbursed Products; and (b) the preparation, or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to any applicable review committees." Id. at pp. 2-3.

314. Critically, at the time Dr. Fitzer spoke with Mr. Didio regarding Allergan's quota, Mr. Dido was a "Covered Employee" and a "Relevant Covered Employee" under the operative CIA.

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[15] The United States Department of Justice, *Allergan Agrees to Plead Guilty and Pay $600 Million to Resolve Allegations of Off-Label Promotion to Botox®*, available at https://www.justice.gov/opa/pr/allergan-agrees-plead-guilty-and-pay-600-million-resolve-allegations-label-promotion-botox (last visited May 10, 2021).

[16] Id.

315. The CIA required "Relevant Covered Persons" to complete at least three hours of specific training. Id. at pp. 2-3, 17.

316. The training was required to cover things like:

a. "all applicable Federal health care program requirements relating to Promotional Functions and/or Product Related Functions"

b. "the personal obligation of each individual involved in Promotional Functions and/or Product Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements"

c. "the legal sanctions for violations of the applicable Federal health care program and FDA requirements"

d. "examples of proper and improper practices related to Promotional Functions and/or Product Related Functions"

Id. at pp. 17-18.

317. The CIA also required Allergan to make the promotion of, and adherence to, a *Code of Conduct*, a condition of employment. Id. at p. 8.

318. The Code of Conduct set forth and was required to continue to include the following minimum requirements:

a. Allergan's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health program requirements and FDA requirements.

b. Allergan's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with Allergan's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

c. Allergan's requirement that all of Allergan's Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by Allergan, suspected violations by Allergan or persons acting on behalf of Allergan of any Federal health care program and FDA requirements or of Allergan's own Policies and Procedures; and

> d. The right of individuals to use the Disclosure Program described in Section III.E, and Allergan commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Id. at pp. 8-9.

319. The CIA required that the Code of Conduct be distributed to each Covered Person and each Covered Person was required to certify, in writing or electronically, that he or she "received, read, understood, and shall abide by Allergan's Code of Conduct." Id. at p. 9. Covered persons were required to certify the same for any revised Code of Conducts. Id.

320. Additionally, the CIA required Allergan to implement written Policies and Procedures "regarding the operation of the Compliance Program and Allergan's compliance with Federal health care program and FDA requirements (Policies and Procedures)". Id.

321. The Policies and Procedures must address, among other things, appropriate ways to conduct Promotional Functions and Product Relating Functions in compliance with all applicable Federal healthcare program requirements, including the AKS and the FCA. (Id. at pp. 10-11).

322. Further, Defendant Allergan's CEO was a "Certifying Employee" as defined in the CIA, meaning he was expected "to monitor and oversee activities within their areas of authority" as well as "annually certify, in writing or electronically, that the applicable Allergan component is compliant with Federal health care program requirements, FDA requirements, and the obligations" of the CIA. Id. at p. 7.

323. Through at least the CIA, Didio specifically and Defendant Allergan generally were on notice that Allergan must comply with all Federal health care program and FDA requirements, including the AKS and FCA. Yet, Allergan never attempted to satisfy the conditions of the AKS referral service safe harbor.

324. What is more, Allergan acknowledged in their 2010 Annual Report what their obligations were as it relates to the AKS, stating in part:

> We are also subject to various federal and state laws pertaining to health care "fraud and abuse" and gifts to health care practitioners. For example, the federal Anti-Kickback Statute makes it illegal to solicit, offer, receive or pay any remuneration, directly or indirectly, in cash or in kind, in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular product, for which payment may be made under government health care programs such as Medicare and Medicaid. The U.S. federal government has published regulations that identify "safe harbors" or exemptions for certain practices from enforcement actions under the Anti-Kickback Statute. We seek to comply with the safe harbors where possible. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, recent health care reform legislation has strengthened these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

325. The CIA was binding on Apollo when it purchased the LAP-BAND® division:

> In the event that, after the Effective Date, Allergan proposes to sell any or all of its business units or locations related to Promotional Functions or Product Related Functions that are subject to this CIA, Allergan shall notify OIG of the proposed sale no later than 5 days after the date the sale is publicly disclosed by Allergan. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. **This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.**

Id. at 42 (emphasis added).

VII) DEFENDANT APOLLO CONTINUES ILLEGAL PRACTICES FOLLOWING ACQUISITION OF ALLERGAN OBESITY INTERVENTION DIVISION.

326. All three of the Allergan employees and executives with whom Dr. Fitzer communicated with about the quota transferred to Apollo in connection with the sale of the LAP-BAND® division.

327. By way of example, Paul Hickey seems to have simultaneously worked at Allergan and served as the Northeast Regional Sales Director for Apollo from December 2013 until June 2014. Hickey described his role at Apollo as:

> Transition sales team and client base over to Apollo Endosurgery, who acquired the Lapband Bariatric surgery device business unit from Allergan Medical in 2013. Increased role to refocus/rebrand the Lapband towards a lower BMI patient market. Develop direct to consumer advertising, manage quarterly budget and realign business relationships **to stabilize the diminishing national gastric band market.**

(emphasis added).

328. As recently as 2017, Jeff Stitely stated that he was the "Surgical Account Manager at Apollo Endosurgery (Allergan)" from "December 2012 – present" and described his responsibilities as "Medical Implant/Device Sales – Lap-Band AP System (Adjustable Gastric Banding/Bariatric Surgery)."

329. Mark Didio also went to Apollo.

330. Unsurprisingly, Apollo continued Allergan's policies. They did not re-instate Dr. Fitzer or other surgeons who were purged by Allergan; and they maintained the practice of allowing only a few, select physicians on its locator.

331. Despite Dr. Fitzer's continued exclusion from www.lapband.com referral service, Defendant Apollo did encourage Dr. Fitzer to use more LAP-BAND®'s.

332. For example, in March 2014, Kristen Graham, an Apollo Surgical Account Manager, called and emailed Dr. Fitzer to encourage additional use of the LAP-BAND® with no mention of quality-of-care issues as previously raise by Defendant Allergan.

333. Further, Ms. Graham forwarded an email from Apollo's Strategic Business Manager, Holly Hoefer, to Dr. Fitzer. The email encouraged account managers to explain to physicians how to track the marketing that Apollo does on their behalf.

334. Ms. Hoefer also worked for Allergan before joining Apollo as a Strategic Business Manager. She described her in part as:

> Medical Practice Operations and Communications Specialist across U.S. for Apollo surgical partners and training expert for Market Development Managers (MDM's). Primary role included sales force training for the development and implementation of business solutions for surgical practices that utilize Apollo Endosurgery devices: Lap Band, Overstitch, and Orbera.

335. Ms. Hoefer's email instructed account managers to request physicians track the marketing that Apollo did on their behalf. The email from the Defendants' medical practice communications specialist who, in her own words, operated across the U.S., was transmitting the Defendants' objective: ensuring surgeons knew of the value Apollo provided on their behalf.

336. The email is further evidence that Apollo intended for surgeons to be aware of the deal they offered: free marketing services could be had in exchange for product loyalty.

337. Additionally, Dr. Fitzer had a conversation with Dr. Mario Morales following Apollo's acquisition of Allergan's obesity division.

338. In November 2014, Dr. Morales mentioned to Dr. Fitzer that he had learned from his practice manager that the insertion of enough LAP-BAND®'s leads to a listing on www.lapband.com. Dr. Morales said that his practice manager heard about this from Defendant Apollo's account manager. Both Dr. Morales and his then partner were noted by Dr. Fitzer to have newly obtained LAP-BAND® listings at that time.

339. Access to the website and physician locator was based upon business requirements, i.e., volume of referrals, as set by Allergan and as maintained by Apollo.

340. Defendant Apollo maintained a form of the quota through at least 2018.

341. Apollo continued Allergan's practice of referring to listed surgeons on www.lapband.com as "Specialists" following its acquisition, again, without providing any public explanation as to what would qualify a surgeon to be a specialist until 2015.

342. What is more, Defendant Apollo misleadingly directed consumers to use a "LAP-BAND® Specialist" by using their locator tool. By way of example, on November 29, 2014, lapband.com stated:

343. The chart below summarizes some iterations of Defendants' requirements for inclusion on the physician locator as found on www.lapband.com:

Date of Public Website Version	Summary Description of Inclusion Criteria on lapband.com
From at least 2012 to March 9, 2015	No listing of criteria identified publicly
March 9, 2015	"This list was created to support persons who want to learn more about the LAP-BAND® procedure by helping connect them to surgeons who currently have demonstrated qualifications and interest in providing good quality care using the LAP-BAND® system. The criteria for inclusion includes: (1) have recently completed all necessary training needed to perform a laparoscopic adjustable gastric banding produces using the LAP-BAND®; (2) have performed a minimum number of surgeries using the LAP-BAND® over the last 12 months; and/or (3) have expressed a strong interest in educating and assisting patients regarding LAP-BAND® procedures. The surgeons on this list pay no fee for inclusion. Some surgeons on this list may be parties in a co-marketing agreement with the company or otherwise provide services to the company from time-to-time. All surgeons on this list have completed the FDA-mandated training on the safe and effective use of the LAP-BAND®."
July 7, 2015	"This list was created to support persons who want to learn more about the LAP-BAND® procedure by helping connect them to surgeons who currently have demonstrated qualifications and interest in providing good quality care using the LAP-BAND® system. The criteria for inclusion are: (1) have demonstrated a strong interest in education and assisting patients regarding LAP-BAND® and completed a LAP-BAND® training course over the last 6 months; or (2) have performed twenty or more surgeries using the LAP-BAND® over the last 12 months.

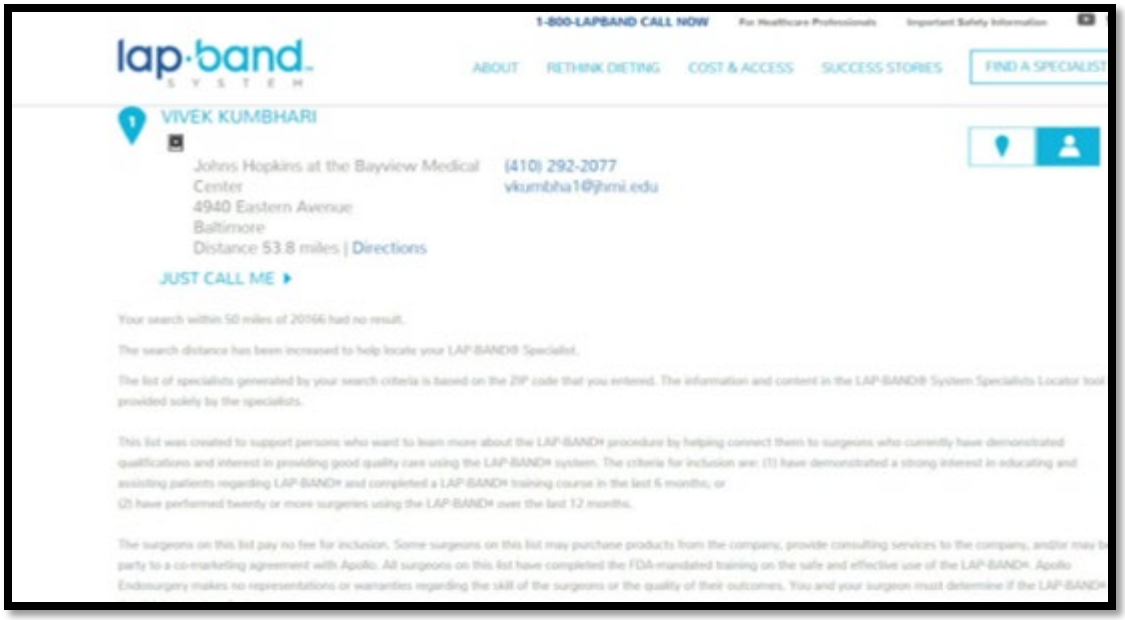
	The surgeons on this list pay no fee for inclusion. Some surgeons on this list may purchase products from the company, provide consulting services to the company, and/or may be a party to a co-marketing agreement with Apollo. All surgeons on this list have completed the FDA-mandated training on the safe and effective use of the LAP-BAND®."
September 22, 2016	"This list was created to support persons who want to learn more about the LAP-BAND™ procedure by helping connect them to surgeons who currently have demonstrated qualifications and interest in providing good quality care using the LAP-BAND™ system. The criteria for inclusion are: (1) have demonstrated a strong interest in education and assisting patients regarding LAP-BAND™ and completed a LAP-BAND® training course in the last 6 months; or (2) have performed twenty or more surgeries using the LAP-BAND™ over the last 12 months. The surgeons on this list pay no fee for inclusion. Some surgeons on this list may purchase products from the company, provide consulting services to the company, and/or may be a party to a co-marketing agreement with Apollo. All surgeons on this list have completed the FDA-mandated training on the safe and effective use of the LAP-BAND™."
October 19, 2017	"This list was created to support persons who want to learn more about the LAP-BAND® procedure by helping connect them to surgeons who currently have demonstrated qualifications and interest in providing good quality care using the LAP-BAND® system. The criteria for inclusion are: (1) has completed a LAP-BAND® training course; or (2) is affiliated with a facility that has performed 15 or more surgeries using the LAP-BAND® over the last 12 months. Premier Practice: Physician is affiliated with a facility or practice that has performed 30 or more surgeries using LAP-BAND in the last 12 months. … The surgeons on this list pay no fee for inclusion. Some surgeons on this list may purchase products from the company, provide consulting services to the company, and/or may be a party to a co-marketing agreement with Apollo. All surgeons on this list have completed the FDA-mandated training on the safe and effective use of the LAP-BAND®."
June 20, 2018	"This list was created to support persons who want to learn more about the LAP-BAND® procedure by helping connect them to surgeons who currently have demonstrated qualifications and interest in providing good quality care using the LAP-BAND® system. The criteria for inclusion are: (1) has completed a LAP-BAND® training course; or (2) is affiliated with a

	facility that has performed 15 or more surgeries using the LAP-BAND® over the last 12 months. Premier Practice: Physician is affiliated with a facility or practice that has performed 30 or more surgeries using LAP-BAND® in the last 12 months. … The surgeons on this list pay no fee for inclusion. Some surgeons on this list may purchase products from the company, provide consulting services to the company, and/or may be a party to a co-marketing agreement with Apollo."

344. Of course, this valuable internet marketing represents remuneration irrespective of its tie to the volume of LAP-BAND® procedures.

345. Defendant Apollo continued Allergan's practice of manipulating the referral database of physicians.

346. In fact, on or about July 31, 2015, when a search was conducted using Apollo's physician locator by entering the zip code of Dr. Fitzer's medical office in Reston, Virginia (20166), the search indicated that there were no LAP-BAND® Specialists in a 50-mile radius of 20166 and that the nearest LAP-BAND® care provider was some 53 miles away in Baltimore: Dr. Vivek Kumbhari. A snapshot of Dr. Kumbhari's www.lapband.com listing as of July 31, 2015, appeared as follows:



347. Dr. Kumbhari, however, is a gastroenterologist—a non-surgeon physician.[17]

348. While Defendant Apollo had no appropriate medical reason to justify the promotion of Dr. Kumbhari since he does not perform surgery and did not meet their advertised criteria, Defendant Apollo had a financial incentive to do so. This was at least one instance where Apollo went beyond promoting the LAP-BAND® device itself on www.lapband.com.

349. While he is not qualified to do surgery, Dr. Kumbhari does do transoral flexible endoscopy (endoscopy). He used endoscopy to perform a then- experimental weight-loss procedure called the endoscopic sleeve gastroplasty (ESG).

350. Also, he would very soon offer Defendant Apollo's Orbera balloon. The Orbera was approved by the FDA in the weeks after Dr. Kumbhari's inexplicable debut on the www.lapband.com locator.

[17] While it is unknown whether Dr. Kumbhari was at John Hopkins while Allergan was owner of www.lapband.com, Dr. Kumbhari was not a surgeon.

351. Defendant Apollo was the only vendor that sold the equipment necessary to perform ESG, specifically the Overstitch™ device, and they owned the Orbera.

352. At the time of this search result, Dr. Kumbhari was one of the only East Coast's only practitioners of the ESG, and within a few weeks, he became one of the only practitioners of the Orbera.

353. There was no other locator at the time that Dr. Kumbhari would have qualified for. Thus, placing Dr. Kumbhari on the www.lapband.com locator could not have been mistaken for a listing intended for any other website, it was intentional.

354. Apollo had not expanded the criteria for inclusion on the physician locator at the time Dr. Kumbhari, a non-surgeon, was listed on the locator.

355. In fact, Dr. Kumbhari's inclusion was in direct contravention of the inclusion criteria provided for on Apollo's website at the time Dr. Kumbhari was listed, which said:

> This list was created to support persons who want to learn more about the LAP-BAND® procedure by helping connect them to surgeons who currently have demonstrated qualifications and interest in providing good quality care using the LAP-BAND® system. The criteria for inclusion are: (1) have demonstrated a strong interest in education and assisting patients regarding LAP-BAND® and completed a LAP-BAND® training course over the last 6 months; or (2) have performed twenty or more surgeries using the LAP-BAND® over the last 12 months.

356. Further, Dr. Fitzer was professionally acquainted with Dr. Kumbhari at the time the listing appeared, and it was clear both from Dr. Fitzer's personal knowledge and Dr. Kumbhari's published credentials that Dr. Kumbhari was unqualified to perform LAP-BAND® implantation or any other kind of surgery. Meanwhile, of course, many qualified surgeons were not included on the LAP-BAND® locator, including Dr. Fitzer.

357. As alleged, Defendant Apollo continued to use www.lapband.com to facilitate unlawful inducements following its acquisition of Allergan's obesity intervention division.

358. Neither Allergan nor Apollo is an independent credentialing authority. Both are medical device manufacturers. It is unclear who or what would give Defendants the authority to certify select surgeons as "Specialists." The designations of physicians as "Specialists" or "Premier Practice" on a website maintained by the manufacturer were a marketing phenomenon. Those designations were useful to surgeons, and they reflect another bit of remuneration offered to physicians to incentivize recommending LAP-BAND® related services and products.

VIII) DEFENDANTS' INDUCEMENTS WERE ILLEGAL AND CAUSED SUBMISSION OF FALSE OR FRAUDULENT CLAIMS.

359. Defendants provided surgeons with access to their website, free marketing, free publicity, and free patient referrals through their physician locator. In return, they required product loyalty.

360. Compared to other general surgery subspecialties, bariatric surgery practices are far more dependent on marketing and outreach to attract the patient interest necessary to stay viable. Marketing is essential and it is commonplace even for small bariatric practices to spend tens or hundreds of thousands of dollars annually on marketing.

361. Access to the services provided free by Defendants saved participating surgeons substantial money and provided surgeons with independent value because it allowed them to forego or reduce their own online advertising.

362. Defendants knowingly conditioned access to these benefits on a business consideration, namely that surgeons would perform LAP-BAND® procedures, in exchange for those benefits, as opposed to other bariatric procedures irrespective of the best interests of the patients.

363. At least one purpose of this access was to induce surgeon referrals, i.e., to cause surgeons to perform bariatric procedures on patients using the LAP-BAND® product as opposed to other weight-loss options.

364. Several of the providers that Defendants remunerated through their physician locator at relevant times were simultaneously being reimbursed by Medicare for LAP-BAND® implantation procedures.

365. The CMS Manual System published Billing Requirements for Bariatric Surgery for Treatment of Morbid Obesity. It defined the code—specifically the Healthcare Common Procedure Coding System (HCPCS) code—that Medicare recognized for adjustable gastric band surgery claims:

> For services on or after February 21, 2006, the following HCPCS codes apply for bariatric services:
>
> • 43770 Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band (gastric band and subcutaneous port components).

366. The submission of a Medicare claim containing code 43770, therefore, necessarily means that an adjustable gastric band procedure was performed, which means that at least one unit of either (1) the LAP-BAND® device or (2) the Realize® device was used during the operation.

367. Since at least 2012, CMS has published provider usage data for beneficiaries enrolled in Medicare.[18] Today, this CMS data is available in the form of "a searchable database that allows you to look up a provider by National Provider Identifier (NPI), or by name and location. The look-up tool will return information on services and procedures provided to beneficiaries enrolled in Original Medicare (fee-for-service), including use information, Medicare

[18] When Dr. Fitzer initially reviewed the data, it was in the form of a downloadable data set.

payment amounts, and submitted charges organized by Healthcare Common Procedure Coding System (HCPCS) code."[19]

368. The data covers a calendar year and contains "100% final-action physician/supplier Part B non-institutional line items for the Medicare fee-for service (FFS) population[.]" The data is populated from the Medicare physician and other practitioners.[20]

369. Claims are reported based on the calendar year the service was rendered. This fact was confirmed for Relator directly by CMS. For example, if a Part B provider performed a service on December 25, 2020, and submitted the claim on January 5, 2021, the claim would be assigned to the 2020 CMS data set because the service rendered was in 2020.

370. The two tables below provide a sample of providers who used the LAP-BAND® device when performing adjustable gastric banding procedures (code 43770) for which they were ultimately reimbursed by Medicare (the reimbursement amounts below do not include the actual cost of the LAP-BAND® device).

371. Dr. Fitzer has personal knowledge from his investigations (explained further below) that the physicians below exclusively performed LAP-BAND® gastric-band surgeries and had listings on Defendants' physician locator tool in 2013. The following table includes Medicare paid claims with dates of service in 2013:[21]

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[19] https://data.cms.gov/tools/medicare-physician-other-practitioner-look-up-tool; *see also* https://www.cms.gov/newsroom/data.

[20] *Id*.

[21] Physicians in these two tables were not qualified (meaning they did not have the requisite certification as described in paragraph 306) to perform the one alternative device, the Realize® device, which was available for use in adjustable gastric banding. Their claims represent claims for LAP-BAND® surgery.

National Provider Identifier	Name[22]	Credentials	State Code	LINE_SRVC_CNT[23]	BENE_UNIQUE_CNT[24]	BENE_DAY_SRVC_CNT[25]	AVERAGE_MEDICARE_ALLOWED_AMT[26]	AVERAGE_SUBMITTED_CHRG_AMT[27]	AVERAGE_MEDICARE_PAYMENT_AMT[28]
1174566996	JOHN GROVES	MD	AL	29	29	29	$495.51	$3,327.59	$392.81
1265475909	STEPHEN BRITT	MD	AL	28	28	28	$664.38	$3,714.29	$519.00
1184628885	GREGG GINSBURG	MD	MO	24	24	24	$1098.24	$4,545.78	$865.88
1801875679	FREDERICK TIESENGA	MD	IL	36	36	36	$1296.11	$3,865.00	$994.39
1609860196	JEFFREY HOLLOWAY	MD	NE	31	29	29	$668.39	$2,845.16	$524.10
1215035779	KEVIN MARTIN	PA-C	NC	19	19	19	$72.05	$657.00	$56.79
1821197609	JOHN JOHNSON	MD	NC	22	22	22	$513.40	$3,180.48	$404.43
1063404028	PANDURANGAN	MD	FL	35	35	35	$634.96	$1,539.69	$499.03

[22] Out of an abundance of caution, Relator removed Keith McEwen from Tables 1 and 2 after uncovering a lone piece of information that suggested the possibility that, at some point Dr. McEwen may have been Realize® band qualified even if he did not perform the procedure.
[23] Number of services provided. CMS, *CMS Medicare Fee-For-Service Provider Utilization & Payment Data Physician and Other Supplier Public Use File: A Methodological Overview*, at p. 6, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Downloads/Medicare-Physician-and-Other-Supplier-PUF-Methodology.pdf (last visited May 10, 2021).
[24] Number of distinct Medicare beneficiaries receiving the service. Id. at p. 7.
[25] Number of distinct Medicare beneficiary/per day services. Id. at p. 7.
[26] Average of the Medicare allowed amount for the service; this figure is the sum of the amount Medicare pays, the deductible and coinsurance amounts that the beneficiary is responsible for paying, and any amounts that a third party is responsible for paying. Id. at p. 7.
[27] Average of the charges that the provider submitted for the service. Id. at p. 7.
[28] Average amount that Medicare paid after deductible and coinsurance amounts have been deducted for the line item service. Id. at p. 7.

	KRISHNARAJ								
1023054640	DAVID ROHRER	MD	MT	21	21	21	$1086.22	$1,140.53	$847.84
1689670069	AHMAD BALI	MD	WV	26	26	26	$1074.26	$5,000.00	$848.17
1619059334	JOHN MOBLEY	MD	OH	19	19	19	$64.58	$134.39	$50.67
1144281445	CARLOS GODINEZ	MD	TX	11	11	11	$124.33	$10,000	$97.47
1225057680	JOSEPH WRIGHT	MD	TX	27	26	27	$633.21	$10,000	$497.70
1568484327	GERARDO CARCAMO	M.D	TX	11	11	11	$825.68	$10,000	$647.92
1013919273	JOHN OLSOFKA	MD	KY	34	34	34	$393.55	$2,647.06	$310.21
1508868753	VINCENT LUSCO	MD	KY	36	36	36	$244.50	$2,600.00	$171.94
1174581813	MARK WATSON	MD	TX	17	17	17	$1084.85	$4,500.00	$856.31

372. Dr. Fitzer has personal knowledge from his investigations that the physicians below exclusively performed LAP-BAND® surgeries and had listings on Defendants' physician locator tool in 2014. The following table includes Medicare paid claims with dates of service in 2014:

National Provider Identifier[29]	Name	Credentials	State Code	LINE_SRVC_CNT	BENE_UNIQUE_CNT	BENE_DAY_SRVC_CNT	AVERAGE_MEDICARE_ALLOWED_AMT	AVERAGE_SUBMITTED_CHRG_AMT	AVERAGE_MEDICARE_PAYMENT_AMT
1689670069	AHMAD BALI	MD	WV	28	28	28	$1089.17	$5000	$849.79
1265475909	STEPHEN BRITT	MD	AL	28	28	28	$469.60	$3214.29	$367.37
1184628885	GREGG GINSBURG	MD	MO	35	35	35	$1085.87	$4485.22	$844.24
1174566996	JOHN GROVES	MD	AL	28	28	28	$751.90	$3857.14	$589.36
1609860196	JEFFREY HOLLOWAY	MD	NE	29	29	29	$702.87	$3000	$524.39
1063404028	PANDURANGAN KRISHNARAJ	MD	FL	15	15	15	$480.94	$1907.83	$377.06
1508868753	VINCENT LUSCO	MD	KY	20	20	20	$267.91	$2999.99	$210.04
1619059334	JOHN MOBLEY	MD	OH	33	33	33	$975.18	$2389	$738.27
1013919273	JOHN OLSOFKA	MD	KY	20	20	20	$379.53	$3000.00	$297.55
1023054640	DAVID ROHRER	MD	MT	19	19	19	$1007.96	$1242.85	$790.24
1801875679	FREDERICK TIESENGA	MD	IL	34	33	33	$1287.08	$3786.77	$1009.07
1174581813	MARK WATSON	MD	TX	11	11	11	$1076.00	$4500	$843.58
1225057680	JOSEPH WRIGHT	MD	TX	11	11	11	$565.96	$10000	$433.24

373. Dr. Fitzer identified the providers in the two tables above were not Realize® band qualified (and therefore could not have implanted a Realize® band) through a process of elimination. Specifically, in or about March of 2013 and again in November of 2014, Dr. Fitzer

[29] The definitions provided in Table 1, footnotes 23-28, equally apply to Table 2.

compiled a list of all self-reported gastric-band surgeons from the American Society of Metabolic and Bariatric Surgeons ("ASMBS").[30]

374. Next, he determined which of those surgeons had listings on www.lapband.com by searching the LAP-BAND® locator for each name.

375. From this list of surgeons, he proceeded to eliminate those who were Realize® band certified. He did this by first confirming whether the surgeons appeared on the Realize® locator.

376. By studying whether the many bariatric surgeons of his acquaintances had Realize® locator listings, Dr. Fitzer learned that when a surgeon lacked a Realize® locator listing, it very reliably indicated that they did not have Realize® certification.

377. Dr. Fitzer thus eliminated about half his list.

378. If Dr. Fitzer did not find the LAP-BAND® Specialist on www.realize.com he subsequently located the provider's professional website, online profiles, and listings on obesityhelp.com and bariatricpal.com. On these sites, it was common practice for bariatric surgeons to provide their accreditation status, including whether they had a Realize® band certification. Dr. Fitzer removed any surgeon for whom he could find evidence of Realize® band certification.

379. In fact, in the course of researching Realize® certifications, Dr. Fitzer found that some of the Medicare-claimant surgeons explicitly held themselves out as users only of the LAP-

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[30] In verifying that all the above claims relate to LAP-BAND® procedures, it is worth noting that the LAP-BAND® device consistently held greater market share as compared to the Realize® device. As of 2010, LAP-BAND® had about 70% of the market share leaving only 30% to the Realize® device. By 2013, it was estimated that LAP-BAND® had about 90% of the market share. *See* https://www.generalsurgerynews.com/Opinion/Article/10-13/Bariatric-Procedures-Decline-Despite-Rise-in-Obesity-and-Diabetes/24135;
https://www.nytimes.com/2010/12/02/business/02obese.html.

BAND® device. Dr. Fitzer removed all surgeons from his list that stated they were Realize® band certified on any of these sites.

380. When the Part B Medicare utilization data was released, Dr. Fitzer cross-referenced the list of surgeons against it to identify those who submitted Medicare claims for services in that year.

381. In 2016, Ethicon discontinued the sale of the Realize® device.

382. Dr. Vito Bagnato, another surgeon, had a listing on www.lapband.com at least in 2014 and 2017, which Dr. Fitzer observed. Dr. Bagnato submitted claims for Medicare reimbursement for code 43770 with for dates of service in 2017, for which he was ultimately reimbursed. Specifically, for dates of service in 2017, Dr. Bagnato was reimbursed for services related to 12 LAP-BAND® device implantations. These occurred after the Realize® device was discontinued; therefore, the following claims can only reflect surgeries for the implantation of the LAP-BAND® device:

National Provider Identifier	Name	Credentials	State Code	Tot_Benes[31]	Tot_Srvcs[32]	Tot_Bene_Day_Srvcs[33]	[34]Average_Medicare_Allowed_amt	[35]Average_Submitted_	[36]Average_Medicare_Payment_am
1508853219	Bagnato Vito	MD	GA	12	12	12	$1058.29	$8000	$834.32

383. The pressure caused by Defendants' free marketing and quota system impaired surgeons' ability to give bias-free information to patients about the procedure that is most medically appropriate for them. Defendants' illegal scheme corrupted the physician/patient relationship.

384. Further, the sales quota also "impose[d] a condition on the manner" in which the surgeon provided the services: The numerical condition put pressure on surgeons to increase sales in exchange for website listings. This pushed physicians to advise patients to undergo the LAP-BAND® procedures more frequently and order more LAP-BAND® devices than they otherwise would. See 42 C.F.R. § 1001.952(f)(3). Surgeons lacked incentive to learn alternative procedures given this arrangement.

385. During the time Defendants implemented the quota, many LAP-BAND® "Specialists" significantly increased Medicare-reimbursed LAP-BAND® device implantations.

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[31] This means "[n]umber of distinct Medicare beneficiaries receiving the service for each Rndrng_NPI, HCPCS_Cd, and Place_Of_Srvc." *See https://data.cms.gov/resources/medicare-physician-other-practitioners-by-provider-and-service-data-dictionary*

[32] This refers to the number of services provided. *Id.*

[33] This refers to the number of distinct Medicare beneficiary/per day services. *Id.*

[34] This refers to the "[a]verage of the Medicare allowed amount for the service; this figure is the sum of the amount Medicare pays, the deductible and coinsurance amounts that the beneficiary is responsible for paying, and any amounts that a third party is responsible for paying."

[35] This refers to the "[a]verage of the charges that the provider submitted for the service. *Id.*

[36] This refers to the "[a]verage amount that Medicare paid after deductible and coinsurance amounts have been deducted for the line item service." *Id.*

386. By way of example, the following surgeons were listed on the www.lapband.com as a "Specialist" and implanted the following number of LAP-BAND® devices (code 43770) in 2012 and 2013:

NPI	Last[37]	First	State	2012 Lap-Bands	2013 Lap-Bands
1609860196	HOLLOWAY	JEFFREY	NE	23	31
1063404028	KRISHNARAJ	PANDURANGAN	FL	15	35
1801875679	TIESENGA	FREDERICK	IL	16	36
1225057680	WRIGHT	JOSEPH	TX	18	27

387. While LAP-BAND® device sales deteriorated nationally, as illustrated above, some Specialists implanted more LAP-BAND® devices, in some cases more than doubling the number of Medicare-reimbursed LAP-BAND® device implants during the quota.

388. Another surgeon who had a listing on the locator in 2012 and 2013 and who also submitted claims to Medicare for implantation of a gastric-band device (code 43770) in 2012 and 2013, was Richard Dicicco. Dr. Fitzer specifically observed Dr. Dicicco's profile on the LAP-BAND® locator as early as 2011. While Dicicco was Realize® band certified (unlike the surgeons in the chart above), Dicicco told Dr. Fitzer personally that he had only ever implanted about 10 Realize® bands total in his entire career, as LAP-BAND® was his preferred band choice. In 2012, Dr. Dicicco implanted and received payment for 26 gastric-bands and 31 gastric-bands in 2013, totaling 57 gastric-band. As his total Medicare claims (57) exceed ten (his total ever Realize® bands irrespective of payor), at least 47 of his Medicare claims during that year were for the LAP-BAND® device. Furthermore, these claims were all for Medicare gastric-bands (as opposed to

[37] Relator removed James Atkinson from the Chart as initially provided in the Third Amended Complaint, as he was not previously listed in the tables above.

private insurance), and thus only reflect a small portion of the LAP-BAND® implants that he performed.

389. Until at least around March of 2015, Defendants did not disclose to website visitors the terms of participation for any of the listed surgeons, nor did they follow the requirements for disclosure of a referral service to the potential patients. See 42 C.F.R. § 1001.952(f)(4).

390. Defendants' quota related to quantity rather than quality of work, which is best illustrated by the fact that Defendants excluded physicians, like Dr. Fitzer, from the locator who were otherwise qualified and authorized to perform LAP-BAND® procedures.

391. Defendants' website access and free marketing, granted or withheld, especially inclusion on the physician locator, provided substantial value to surgeons and qualifies as a kickback scheme, which was nationwide in scope, and as unlawful referrals in violation of the Anti-Kickback Statute.

392. In addition, there are numerous state laws and regulations that prohibit kickbacks in medical coverage and health care plans. See, e.g., Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001, et seq.

393. Defendants did not comply with the requirements for a referral service to qualify under the safe-harbor provisions of the Anti-Kickback Statute, and adherence to each requirement is necessary to qualify for the safe-harbor exception.

394. Defendants knew or should have known that surgeons in their physician locator performed LAP-BAND® procedures for patients enrolled in federal programs, such as Medicare or Medicaid.

395. Defendants knew or should have known that these programs required surgeons to certify compliance with federal laws, such as the Anti-Kickback Statute.

396. Compliance with the Anti-Kickback Statute is a material condition of payment under federal health programs. United States ex rel. Nevyas v. Allergan, Inc., No. 2:09-cv-0043-MAK, 2015 WL 3429381, at *2 (E.D. Pa. May 26, 2015) (denying Defendant's motion to dismiss Relator's False Claims Act claim in case where Relator alleged Allergan caused to be presented claims tainted by scheme to induce physicians to write prescriptions for Allergan products by providing them illegal remuneration); see also Second Amended Complaint at 3-4, Nevyas, No. 2:09-cv-0043-MAK (explaining that illegal financial inducements included, but were not limited to, access to state-of-the-art website for an annual fee below fair-market-value).

397. Defendants "caused to be presented" to the United States and the listed states claims tainted by Defendants' scheme to induce surgeons to implant their medical devices by providing surgeons remuneration in violation of the Anti-Kickback Statute, making such claims "false or fraudulent' which Defendants knew to be "false or fraudulent." See id. at 2.

398. The data and information described herein demonstrates a pattern of conduct that necessarily led to the submission of false claims in addition to the specific false claims cited above.

399. In addition to the unlawful kick-back scheme, the Plaintiff-Relator also reviewed advertising material produced on the Defendants' website and in other media and found numerous misleading and false statements directed at consumers.

400. Those statements, which pertained to important safety topics like reoperation data, total complications, long-term effect of the device on other medical conditions, and reversal rates, were used to promote the medical device. While some were merely misleading, many were wholly false.

401. Defendants' false statements induced people to use the LAP-BAND® and the governments of the United States and the above listed states to pay claims for these devices and the associated surgeries.

VIOLATIONS OF THE FEDERAL AND STATE FALSE CLAIMS ACTS

COUNT ONE
Violations of 31 U.S.C. § 3729(a)(1)(A)
Presenting False Claims for Payment

402. The allegations contained in the above paragraphs are hereby re-alleged and set forth fully as above.

403. This is a claim for treble damages and civil penalties under the Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

404. As set forth above, the Defendants knowingly caused to be presented, false or fraudulent claims for payment or approval to the United States government in connection with the sale of their LAP-BAND® medical device.

405. The FCA defines a "claim" as "any request or demand…for money or property" that "is presented to an officer, employee, or agent of the United States." 31 U.S.C. § 3729(b)(2).

406. The FCA defines "knowing" and "knowingly" to mean that a person has "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1).

407. Defendants conducted an unlawful kickback scheme by providing surgeons with illegal remuneration, including valuable free advertising on Defendants' website, www.lapband.com, in order to induce surgeons to recommend Defendants' LAP-BAND® medical device instead of alternative operations.

408. Defendants favored LAP-BAND® only surgeons and company officials specifically told Relator he had been removed from the site, because he did not meet Defendants' requirement to perform forty (40) implants of the device in a year.

409. Such false claims were made to and/or paid by United States government programs including, but not limited to Medicare/Medicaid, Tri-Care, and the Veterans Administration.

410. Defendants' scheme to induce surgeons to use the LAP-BAND® product over other alternatives by providing those surgeons remuneration in violation of the Anti-Kickback renders such claims "false or fraudulent."

411. These actions are in violation of the Anti-Kickback Statute, which confers direct liability under the False Claims Act.

412. Furthermore, Defendants' pressure on bariatric surgeons undermined the physicians' ability to fully inform patients about other treatments available for obesity.

413. Such actions undermine the informed consent process, which is not only a central requirement of medical ethics, but also a required condition of participation under Medicare as well as other government medical programs.

414. Undermining the informed consent process creates additional liability for false claims under the Act, because any claim for payment to a government agency involving a LAP-BAND® procedure is made with the implied and or express certification that a true informed consent process was conducted.

415. As a result of the Defendants' fraudulent and or illegal conduct, the United States has directly or indirectly paid numerous false claims.

416. Damages to the United States include, but are not limited to, the full amount it has paid on any such false claims and any related claims for treatment of LAP-BAND® related health services.

417. Defendants are liable to the United States for three times the full amount of these damages to be determined at trial.

418. Each and every such false claim is also subject to a civil fine under the False Claims Act of Five Thousand, Five Hundred Dollars ($5,500.00) to Eleven Thousand Dollars ($11,000.00), plus any increase as specified under the Federal Civil Penalties Adjustment Act of 1990.

COUNT TWO
Violations of 31 U.S.C. § 3729(a)(1)(B)
Use of False Statements and False Certifications

419. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

420. This is a claim for treble damages and civil penalties under the Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

421. As set forth above, Defendants knowingly made, and or caused to be made, false statements and false records in order to obtain payment for LAP-BAND® medical devices and related services, and those false statements were material to the United States government's decision to pay.

422. Pressure by Defendants on surgeons to conduct more procedures using its product undermined the informed consent process. Therefore, the documents that attest to patients granting such informed consent are false records.

423. In addition, bills submitted to Medicare and other government programs for LAP-BAND® related services, which state or imply that the charges were made in conformity with

federal law, including but not limited to, the Anti-Kickback Statute and CMS regulations, are materially false statements.

424. As a result of Defendants' fraudulent and/or illegal conduct, the United States has directly or indirectly paid numerous false claims.

425. Damages to the United States include but are not limited to the full amount it has paid on any such false claims.

426. Defendants are liable to the United States for three times the full amount of these damages.

427. Each and every such false statement or record is also subject to a civil fine under the False Claims Act of Five Thousand Five Hundred Dollars ($5,500.00) to Eleven Thousand Dollars ($11,000.00), plus any increase as specified by the Federal Civil Penalties Adjustment Act of 1990.

COUNT THREE
Violations of Cal. Gov't Code § 12650, et seq.
The California False Claims Act

428. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

429. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code § 12650, et seq.

430. Under the California False Claims Act, the Defendants are liable for any false claim when California or a political subdivision provides any portion of the funds. "Political subdivision" includes any city, city and county, county tax or assessment district or other legally authorized local entity with jurisdictional boundaries.

431. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to the State of

California's Medicaid program ("Medi-Cal"), and to other programs funded by California as well as to programs funded by political subdivisions of California.

432. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

433. The State of California's Medicaid program and any additional program funded by California or funded by any political subdivision of California were unaware of the falsity or fraudulent nature of the claims. Such claims otherwise would not have been paid or allowed.

434. By reason of these payments the State of California and its political subdivisions have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT FOUR
Violations of Colo. Rev. Stat. § 25.5-4-303.5, et seq.
The Colorado Medicaid False Claims Act

435. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

436. This is an action for treble damages and civil penalties for violations of the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §25.5-4-303.5, et seq.

437. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to the State of Colorado for payment under the Colorado Medical Assistance Act.

438. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

439. The State of Colorado's Medicaid program and any program paying under the Colorado Medical Assistance Act were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

440. By reason of these payments the State of Colorado has been damaged and continues to be damaged.

COUNT FIVE
Violations of Conn. Gen. Stat. § 4-274, et seq.
The Connecticut False Claims Act

441. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

442. This is an action for treble damages and civil penalties for violations of the Connecticut False Claims Act, Conn. Gen. Stat. § 4-274, et seq.

443. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to medical assistance programs funded by the State.

444. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

445. The State of Connecticut's medical assistance programs were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

446. By reason of these payments the State of Connecticut has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT SIX
Violations of Del. Code Ann. tit. 6, § 1201, et seq.
The Delaware False Claims and Reporting Act

447. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

448. This is an action for treble damages and civil penalties for violations of Section 1201(a) of the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201, et seq.

449. Under the Delaware False Claims and Reporting Act, the Defendants are liable for any false claims when the Government of Delaware provides any portion of the funds. "Government" includes all departments, boards or commissions of the executive branch of the State, all political subdivisions of the State, the Delaware Department of Transportation, all state and municipal authorities, all organizations created by or pursuant to a statute which declares in substance that such organization performs or has for its purpose the performance of an essential governmental function, and all organizations, entities or persons receiving funds of the State where the act complained of pursuant to this chapter relates to the use of such funds of the State.

450. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Delaware's Medicaid program and other programs funded by the "Government" as "Government" is defined under the Delaware False Claims and Reporting Act.

451. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

452. The State of Delaware's Medicaid program and any additional program funded by the "Government" were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

453. By reason of these payments the State of Delaware has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT SEVEN
Violations of DC Code, § 2-381.01, et seq.
The District of Columbia False Claims Act

454. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

455. This is an action for treble damages and civil penalties for violations of the District of Columbia False Claims Act, DC Code § 2-381.01, et seq.

456. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to the District of Columbia's Medicaid program and to other programs funded by the District of Columbia.

457. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

458. The District of Columbia's Medicaid program and any additional program funded by the District of Columbia were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

459. By reason of these payments the District of Columbia has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT EIGHT
Violations of Fla. Stat. Ann. § 68.081, et seq.
The Florida False Claims Act

460. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

461. This is an action for treble damages and civil penalties for violations of the Florida False Claims Act, Fla. Stat. Ann. § 68.081, et seq.

462. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Florida's Medicaid program as well to other programs funded by the State of Florida.

463. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

464. The State of Florida's Medicaid program and any additional program funded by the State of Florida were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

465. By reason of these payments the State of Florida has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT NINE
Violations of Ga. Code Ann. § 49-4-168, et seq.
The Georgia False Medicaid Claims Act

466. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

467. This is an action for treble damages and civil penalties for violations of the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168, et seq.

468. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Georgia's Medicaid program.

469. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

470. The State of Georgia's Medicaid program was unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

471. By reason of these payments the State of Georgia has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT TEN
Violations of Haw. Rev. Stat. Ann. § 661-21, et seq.
The Hawaii False Claims Act

472. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

473. This is an action for treble damages and civil penalties for violations of the Hawaii False Claims Act, Haw. Rev. Stat. Ann. § 661-21, et seq.

474. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Hawaii's Medicaid program and to other programs funded by the State of Hawaii.

475. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

476. The State of Hawaii's Medicaid program and any additional program funded by the State of Hawaii were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

477. By reason of these payments the State of Hawaii has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT ELEVEN
Violations of 740 Ill. Comp. Stat. Ann. 175/1, et seq.
The Illinois False Claims Act

478. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

479. This is an action for treble damages and civil penalties for violations of the Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. 175/1, et seq.

480. Under the Illinois False Claims Act, the Defendants are liable for any false claim when the State provides any portion of the funds. "State" means the State of Illinois and any agency of State government, the system of State colleges and universities, any school district, community college district, county, municipality, municipal corporation, unit of local government, and any combination of the above under an intergovernmental agreement that includes provisions for a governing body of the agency created by the government.

481. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Illinois' Medicaid program and to other programs funded by the "State" as "State" is defined under the Illinois False Claims Act.

482. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used a false records or statements.

483. The State of Illinois' Medicaid program and any additional program funded by the "State" were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

484. By reason of these payments the State of Illinois has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT TWELVE
Violations of Ind. Code § 5-11-5.5, et seq.
The Indiana False Claims and Whistleblower Protection Act

485. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

486. This is an action for treble damages and civil penalties for violations of the Indiana False Claims Act and Whistleblower Protection Act, Ind. Code § 5-11-5.5, et seq.

487. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Indiana's Medicaid program and to other programs funded by the State of Indiana.

488. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

489. The State of Indiana's Medicaid program and any additional program funded by the State of Indiana were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

490. By reason of these payments the State of Indiana has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT THIRTEEN
Violations of Iowa Code § 685.1, et seq.
The Iowa False Claims Act

491. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

492. This is an action for treble damages and civil penalties for violations of the Iowa False Claims Act, Iowa Code § 685.1, et seq.

493. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Iowa's Medicaid program and other programs funded by the State of Iowa.

494. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

495. The State of Iowa's Medicaid program and other programs funded by the State of Iowa were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

496. By reason of these payments the State of Iowa has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT FOURTEEN
Violations of La. Rev. Stat. Ann. § 46.437.1, et seq.
The Louisiana Medical Assistance Program Integrity Law

497. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

498. This is an action for treble damages and civil penalties for violations of the Louisiana Medical Assistance Program Integrity Law, La. Rev. Stat. Ann. § 46.437.1, et seq.

499. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Louisiana's Medicaid program and or its medical assistance programs.

500. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

501. The State of Louisiana's Medicaid program and any medical assistance program were unaware of the falsity or fraudulent nature of these claims. Such claims would otherwise not have been paid or allowed.

502. By reason of these payments the State of Louisiana has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT FIFTEEN
Violations of Mass. Ann. Laws ch.12, § 5, et seq.
The Massachusetts False Claims Act

503. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

504. This is an action for treble damages and civil penalties for violations of the Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, § 5, et seq.

505. Under the Massachusetts False Claims Act the Defendants are liable for a false claim if the Commonwealth of Massachusetts or its "political subdivisions" provides any portion

of the funds. "Political subdivision" is defined to include any city, town, county or other governmental entity authorized or created by state law, including public corporations and authorities.

506. Through the use of kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to the Commonwealth's Medicaid program, other programs funded by Massachusetts and programs funded by political subdivisions of Massachusetts.

507. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

508. The Commonwealth of Massachusetts' Medicaid program, any additional programs funded by Massachusetts, and any programs funded by political subdivisions of Massachusetts were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

509. By reason of these payments the Commonwealth of Massachusetts and its political subdivisions have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT SIXTEEN
Violations of Mich. Comp. Laws. Serv.§ 400.601, et seq.
The Michigan Medicaid False Claims Act

510. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

511. This is an action for treble damages and civil penalties for violations of the Michigan Medicaid False Claims Act, Mich. Comp. Laws. Serv.§ 400.601, et seq.

512. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Michigan's Medicaid program and or the Michigan Department of Community Health.

513. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

514. The State of Michigan's Medicaid program and the Michigan Department of Community Health were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

515. By reason of these payments the State of Michigan has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT SEVENTEEN
Violations of Minn. Stat. § 15C.01, et seq.
The Minnesota False Claims Act

516. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

517. This is an action for treble damages and civil penalties for violations of the Minnesota False Claims Act, Minn. Stat. § 15C.01, et seq.

518. Under the Minnesota False Claims Act, the Defendants are liable for any false claims if the State of Minnesota or any political subdivision provides any portion of the funds. "Political subdivision" means a political subdivision, or a department or agency of a political subdivision.

519. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Minnesota's Medicaid program, other programs funded by Minnesota, and programs funded by political subdivisions of Minnesota.

520. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

521. The State of Minnesota's Medicaid program, other programs funded by Minnesota, and programs funded by political subdivisions of Minnesota were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

522. By reason of these payments the State of Minnesota and its political subdivisions have been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT EIGHTEEN
Violations of Mont. Code Ann. § 17-8-401, et seq.
The Montana False Claims Act

523. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

524. This is an action for treble damages and civil penalties for violations of the Montana False Claims Act, Mont. Code Ann. § 17-8-401, et seq.

525. Under the Montana False Claims Act the Defendants are liable for any false claim if any Montana governmental entity provides a portion of the funds. "Governmental entity" means the state, any city, town, county school district, tax or assessment district, or other political subdivision of the state, or a unit of the Montana university system.

526. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Montana's Medicaid program, other programs funded by the State of Montana, and Montana governmental entities. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

527. The State of Montana's Medicaid program, and other programs funded by Montana or other Montana governmental entities were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

528. By reason of these payments the State of Montana and its governmental entities have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT NINETEEN
Violations of Nev. Rev. Stat. Ann. § 357.010, et seq.
The Nevada Submission of False Claims to State or Local Government Act

529. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

530. This is an action for treble damages and civil fines for violations of the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. § 357.010, et seq.

531. Under the Nevada Submission of False Claims to State or Local Government Act, the Defendants are liable for false claims if the State of Nevada or a political subdivision provided any portion of the funds. "Political subdivision" means a county, city, assessment district, or any other local government as defined by Nev. Rev. Stat. Ann. § 354.474.

532. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendant knowingly presented or caused to be presented false claims to Nevada's Medicaid program, other programs funded by Nevada, and programs funded by its political subdivisions.

533. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used a false records or statements.

534. The State of Nevada's Medicaid program, other programs funded by Nevada, and programs funded by its political subdivisions were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

535. By reason of these payments, the State of Nevada and its political subdivisions have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT TWENTY
Violations of N.J. Stat. Ann. § 2A:32C-1, et seq.
The New Jersey False Claims Act

536. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

537. This is an action for treble damages and civil fines under the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1, et seq.

538. Under the New Jersey False Claims Act the Defendants are liable for any false claims made if the State provided any of the funds. "State" means any of the principal departments in the Executive Branch of State Government; any division, board, bureau, office, commission or other instrumentality within or created by such department; and any independent State authority, commission, instrumentality or agency.

539. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to New Jersey's Medicaid program, and other programs funded by the "State" as "State" is defined under the New Jersey False Claims Act.

540. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

541. The State of New Jersey's Medicaid program and other programs funded by the "State" were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

542. By reason of these payments the State of New Jersey has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT TWENTY-ONE
Violations of N.M. Stat. Ann. § 27-14-1, et seq. and
Violations of N.M. Stat. Ann. § 44-9-1, et seq.
The New Mexico Medicaid False Claims Act and
The New Mexico Fraud Against Taxpayers Act

543. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

544. This is an action for treble damages and civil fines under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1, et seq., and the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-1, et seq.

545. Under these laws, the Defendants are liable for any false claims made involving the State of New Mexico's Medicaid program, and other false claims when the State provides any portion of the funds. "State" means the State of New Mexico or any of its branches, agencies, departments, boards, commissions, officers, institutions or instrumentalities, including the New Mexico finance authority, New Mexico Mortgage finance authority, and New Mexico lottery authority.

546. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to New Mexico's Medicaid program, and other programs funded by the "State" as "State" is defined under the New Mexico Fraud Against Taxpayers Act.

547. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

548. The State of New Mexico's Medicaid program and other programs funded by the "State" were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

549. By reason of these payments the State of New Mexico has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT TWENTY-TWO
Violations of N.Y. State Fin. Law § 187, et seq.
The New York False Claims Act

550. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

551. This is an action for treble damages and civil fines under the New York False Claims Act. N.Y. State Fin. Law § 187, et seq.

552. Under The New York False Claims Act, the Defendants are liable for any false claim made if the State of New York or "local government" provides any portion of the funds. "Local government" means any New York county, city, town, village, school district, board of cooperative educational services, local public benefit corporation or other municipal corporation, or political subdivision of the state or of such local government.

553. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to New York's Medicaid program, other programs funded by New York State, and programs funded by New York local governments.

554. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used a false records or statements.

555. The State of New York's Medicaid program, other programs funded by New York State, and programs funded by New York local governments were unaware of the falsity or fraudulent nature of these claims. Such claims would otherwise not have been paid or allowed.

556. By reason of these payments the State of New York and New York local governments have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT TWENTY-THREE
Violations of N.C. Gen. Stat. § 1-605, et seq.
The North Carolina False Claims Act

557. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

558. This is an action for treble damages and civil fines against the Defendants under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605, et seq.

559. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to North Carolina's Medicaid program and other programs funded by the State of North Carolina, and or knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

560. The State of North Carolina's Medicaid program and other programs funded by North Carolina and were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

561. By reason of these payments the State of North Carolina has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT TWENTY-FOUR
Violations of Okla. Stat. tit. 63, § 5053, et seq.
The Oklahoma Medicaid False Claims Act

562. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

563. This is an action for treble damages and civil fines against the Defendants under the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053, et seq.

564. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Oklahoma's Medicaid program and other programs funded by the State of Oklahoma.

565. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

566. The State of Oklahoma's Medicaid program and other programs funded by the State of Oklahoma were unaware of the falsity or fraudulent nature of the claims. Such claims otherwise would not have been paid or allowed.

567. By reason of these payments the State of Oklahoma has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT TWENTY-FIVE
Violations of R.I. Gen. Laws § 9-1.1-1, et seq.
The Rhode Island False Claims Act

568. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

569. This is an action for treble damages and civil fines against Defendants under the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, et seq.

570. Under the Rhode Island False Claims Act the Defendants are liable for any false claim when the State provides any portion of the funds. "State" means the State of Rhode Island,

any agency of state government, and any political subdivision, meaning any city, town, county, or other governmental entity authorized or created by state law, including public corporations and authorities.

571. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Rhode Island's Medicaid program, and other programs funded by the "State" as "State" is defined under the Rhode Island False Claims Act.

572. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

573. The State of Rhode Island's Medicaid program and other programs funded by the "State" were unaware of the falsity or fraudulent nature of the claims. Such claims otherwise would not have been paid or allowed.

574. By reason of these payments the State of Rhode Island has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT TWENTY-SIX
Violations of Tenn. Code Ann. § 4-18-101, et seq. and
Violations of Tenn. Code Ann. § 71-5-181, et seq.
The Tennessee False Claims Act and
Tennessee Medicaid False Claims Act

575. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

576. This is an action for treble damages and civil fines against the Defendants under Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101, et seq., and the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, et seq.

577. Under these laws the Defendants are liable for any false claim if the State of Tennessee or a political subdivision of the State of Tennessee provided any portion of the funds.

578. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Tennessee's Medicaid program, other programs funded by Tennessee, and programs funded by political subdivisions of Tennessee.

579. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

580. The State of Tennessee's Medicaid program, other programs funded by Tennessee, and political subdivisions of Tennessee were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

581. By reason of these payments the State of Tennessee and its political subdivisions have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT TWENTY-SEVEN
Violations of Tex. Hum. Res. Code Ann. § 36.001, et seq.
The Texas Medicaid Fraud Prevention Act

582. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

583. This is an action for treble damages and civil fines against the Defendant under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001, et seq.

584. By way of kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to Texas's Medicaid program. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

585. The State of Texas's Medicaid program was unaware of the falsity or fraudulent nature of the claims. Such claims otherwise would not have been paid or allowed.

586. By reason of these payments the State of Texas has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT TWENTY-EIGHT
Violations of Va. Code Ann. § 8.01-216.1, et seq.
The Virginia Fraud Against Taxpayers Act

587. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

588. Plaintiff-Relator seeks relief against Defendants under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1, et seq.

589. Under the Virginia Fraud Against Taxpayers Act, the Defendant is liable for any false claim if the Commonwealth has provided any portion of the money. "Commonwealth" means the Commonwealth of Virginia, any agency of state government, and any political subdivision of the Commonwealth.

590. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to the Commonwealth of Virginia's Medicaid program and other programs funded by the Commonwealth, as "Commonwealth" is defined under this Act.

591. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

592. The Commonwealth of Virginia's Medicaid program and other programs funded by the Commonwealth, its agencies, and political subdivisions were unaware of the falsity or fraudulent nature of the claims. Such claims otherwise would not have been paid or allowed.

593. By reason of these payments the Commonwealth of Virginia, its agencies and political subdivisions have been damaged and continue to be damaged in a substantial amount to be determined at trial.

COUNT TWENTY-NINE
Violations of Wash. Rev. Code § 74.66.005, et seq.
The Washington Medicaid Fraud False Claims Act

594. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

595. This is an action for treble damages and civil fines against the Defendants under The Washington Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.005, et seq.

596. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to the Washington Medicaid program.

597. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

598. The State of Washington's Medicaid program was unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

599. By reason of these payments the State of Washington has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT THIRTY
Violations of Wis. Stat. Ann. § 20.931, et seq.
The Wisconsin False Claims for Medical Assistance Law

600. The allegations contained in the above paragraphs are hereby re-alleged as set forth fully above.

601. This is an action for treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. Ann. § 20.931, et seq.

602. Through kickbacks, misrepresentations, and interference with the informed consent process, Defendants knowingly presented or caused to be presented false claims to the Wisconsin Medicaid program, and or false claims for medical assistance.

603. Defendants knowingly accomplished these unlawful acts by making, using, or causing to be used false records or statements.

604. The State of Wisconsin's Medicaid program and any State of Wisconsin medical assistance program were unaware of the falsity or fraudulent nature of these claims. Such claims otherwise would not have been paid or allowed.

605. By reason of these payments the State of Wisconsin has been damaged and continues to be damaged in a substantial amount to be determined at trial.

606. While the legislature repealed the law on July 12, 2015 (see 2015 Act 55 § 945n), Wisconsin law provides that "[t]he repeal of a statute hereafter shall not remit, defeat or impair any civil or criminal liability for offenses committed, penalties, or forfeitures incurred or rights of action accrued under each statue before the repeal thereof…" Wis. Stat. Ann. § 990.04.

607. Thus, Relator's claim survives under Wisconsin law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff-Relator, on behalf of himself, the United States, and all States listed herein request that judgment be entered in his favor and against Defendants as follows:

(A) That Defendants cease and desist from violating 31 U.S.C. § 3729, et seq., and the counterpart provisions of the state statutes set forth above;

(B) That this Court enter judgment against the Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than Five Thousand Five Hundred Dollars ($5,500.00) and not more than Eleven Thousand Dollars ($11,000.00) for each violation of 31 U.S.C. § 3729 plus any increase allowed for

such civil penalties as specified under the Federal Civil Penalties Adjustment Act of 1990;

(C) That this Court also enter judgment against the Defendants in the appropriate amount to each of the States for damages and civil fines as determined under the above listed State False Claims Acts;

(D) That Plaintiff-Relator be awarded an amount that the Court decides is reasonable, which shall not be less than Twenty Five Percent (25%) nor more than Thirty Percent (30%) of the proceeds or settlement of any related administrative, criminal, or civil actions, including the monetary value of any equitable relief, fines, restitution, or disgorgement to the United States, States and/or third parties;

(E) That Plaintiff-Relator be granted a trial by jury;

(F) That Plaintiff-Relator, the United States, and the States listed herein be awarded pre-judgment interest;

(G) That the Plaintiff-Relator, be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) and similar provisions of the Sate False Claims Acts listed herein;

(H) That the United States, the States, Sub-divisions, Municipalities, and the Relator recover such other relief as the Court deems just and proper.

JURY TRIAL DEMANDED

608. Plaintiff-Relator hereby demands a jury trial on the causes of action alleged herein.

Respectfully submitted,

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/s/

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/s/(Signed by Rebekah Bailey with Permission from Anthony Munter

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